HERC Coverage Guidance – Hip Surgery Procedures for Femoroacetabular Impingement (FAI) Syndrome
Disposition of 2nd Round of Public Comments

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Commenters

Identification	Stakeholder
A	*American Association of Orthopaedic Surgeons (AAOS)*, Washington, D.C.
B	*Smith & Nephew, Inc.*, Andover, MA
C	*Arthroscopy Association of North America*, Rosemont, Illinois
D	*Andrea Herzka, MD*, Assistant Professor, Dept. of Orthopaedic Surgery and Rehabilitation, OHSU, Portland, OR ***HERC Appointed Expert***

HERC Coverage Guidance – Hip Surgery Procedures for Femoroacetabular Impingement (FAI) Syndrome
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Public Comments

Ident.	#	Comment	Disposition
A	1	Thank you for the opportunity to comment on the draft guidance regarding hip surgery procedures for Femoroacetabular Impingement Syndrome (FAI). The American Association of Orthopaedic Surgeons (AAOS) represents 98% of the orthopaedic surgeons practicing in the United States, 368 of whom practice in Oregon. Orthopaedic surgeons are the preeminent physicians providing medical treatment of musculoskeletal conditions and disease. The AAOS firmly supports the incorporation of evidence into clinical practice, and is actively involved in developing and promoting Evidence Based Clinical Practice Guidelines for a number of musculoskeletal conditions. However, the AAOS opposes the proposed "no coverage" determination put forth by the Health Evidence Review Commission (HERC), because we do not believe this decision is consistent with evidence showing that surgery is a cost-effective treatment for the management of FAI Syndrome. Surgical treatment of FAI for symptomatic patients with ongoing disability issues can provide long- lasting symptom relief and allows these patients to return to work or other desired activities, reducing FAI's economic burden on society.	Thank you for this information.
A	2	The American Medical Association (AMA) concluded that FAI surgery is clinically effective; granting three Category 1 CPT codes effective January 2011. One criterion for granting Category 1 CPT codes is that "the clinical efficacy of the service/procedure is well established and documented in U.S. peer reviewed literature." The AAOS believes that if a service or procedure has a Category I CPT code, it is not experimental or investigational. Therefore, payers should not deny reimbursement for these services and procedures when they are medically necessary. When payers do otherwise, they threaten the health of the public and unjustifiably interfere with the physician/patient relationship.	The existence of a Category I CPT code is not sufficient evidence of effectiveness.
A	3	All national U.S. commercial insurers and Medicare cover FAI surgery because it has been shown to be clinically effective. Since 2008, six independent systematic reviews of FAI surgery have concluded that published evidence supports its safety and effectiveness.	The HTAS is aware of this, but does not reach its conclusions based on the decisions of other payers. References not provided.
A	4	More than 40 peer-reviewed publications for symptomatic FAI using arthroscopic, open, or a combination of these surgical approaches report that patients' symptoms are relieved and they are able to return to their normal activity levels.	References not provided. HTAS is unaware of any studies that were not included in the WA HTA report that are not case series. Case series are highly susceptible to bias and a lower quality type of evidence. However, given the large volume of studies with favorable results, and the likelihood of significant delay in conducting a RCT, HTAS has recommended coverage of surgical correction. ***Relates to discussion question #1***

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A	5	In July 2011, the National Institute for Health and Clinical Excellence in the United Kingdom stated in published guidance on open and arthroscopic FAI surgery, that current evidence of the efficacy of the procedures is adequate for the relief of associated symptoms.	HTAS is aware of the NICE guidance and it is included in the coverage guidance document. Their guidance acknowledges little or no controlled data comparing the procedure with other interventions or natural history. The structure of healthcare delivery in the UK allows them to create a registry to track outcomes. HTAS has elected a similar recommendation, despite the inability to require the use of a registry. ***Relates to discussion question #1***
A	6	The AAOS once gain urges the Committee to revise its coverage guidance on hip surgery procedures for Femoroacetabular Impingement Syndrome (FAI) to be consistent with the other evidence-based coverage determinations and provide access to this safe, effective, and cost-effective treatment to Oregon's public employees and Oregon Health Plan participants. Thank you for your consideration of these comments. Please do not hesitate to contact AAOS if we can be of further assistance.	HTAS has recommended coverage of surgical correction of FAI syndrome.
B	7	Smith & Nephew, Inc. is a global medical technology business specializing in Endoscopy, Orthopedics and Wound Management. We comment on the draft coverage guidance for surgery for Femoroacetabular Impingement (FAI) posted June 27, 2013. **FAI understanding is evolving.** Recognition of FAI as a disorder is a process in evolution. About 70 percent of all the literature on FAI has been published in 2010 or later. (Figure 1) Unrecognized, and/or inappropriately managed symptomatic FAI can lead to inefficient and wasteful use of medical resources.[1]	Thank you for taking the time to comment. HTAS is aware that a large volume of literature has been published since the date of the WA HTA report, but is unaware of any study type other than case series or retrospective cohort studies that were not included in that review (see comment #4). Despite this fact, given the large volume of studies with favorable results, and the likelihood of significant delay in conducting a RCT, HTAS has recommended coverage of surgical correction of FAI syndrome.

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B	8	**Pre-operative diagnosis.** Contrary to the Health Technology Assessment published by Washington State, FAI can reasonably be diagnosed with high probability.[1-4]	• Refs #1 and 2 were published before the date of the WA HTA report (last search date June 2011). The HTAS bases their guidance documents on reviews of the literature that utilize the highest standards of evidence based medicine. Studies are included or excluded based on transparent, reproducible criteria; therefore the HTAS does not investigate individual studies. The HTAS assumes that the conclusions reached by the authors of these reviews weigh all the available evidence in accordance with the principles of evidence based medicine, and does not attempt to re-review the entire body of evidence to reach its own conclusions. • Ref #3 is a SR of arthroscopic treatment of FAI. Authors report "We found that there was great inconsistency among the indications for arthroscopic management of FAI. Clinical and radiographic indices remain largely unvalidated." • Ref #4 is a SR of treatment of FAI using open surgical dislocation. Authors state: "In short, there were major inconsistencies in the reported clinical and radiographic criteria used to indicate surgery among the 15 studies reviewed." and "These results showed that that there

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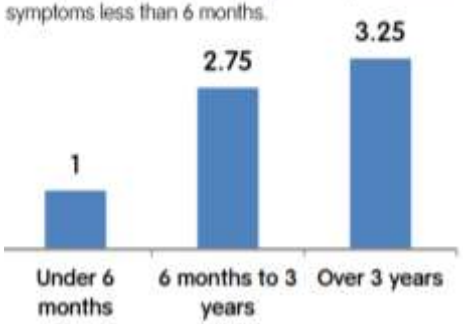
			was an inconsistency between the clinical and radiographic indications for surgical hip dislocation as a treatment for femoroacetabular impingement." • Both of these reviews appear to contradict the commenter's statement.
B	9	**Risk of delaying treatment for FAI.** A recent evaluation of 561 consecutive hip arthroscopy patients (574 procedures: labral tear, 60.8%; FAI, 22.6%; condylar lesions, 16.6%) evaluated three patient segments by duration of symptoms: less than six months, six months to three years and over three years. Repeat arthroscopy on the same side or revision were more common in patients with delayed surgery[5] (Figure 2). **Figure 2. Hip Arthroscopy in 561 patients** Relative risk of revision hip arthroscopy or arthroplasty on same side compared to patients with symptoms less than 6 months.  	This is a consecutive case series that compares outcomes based on length of symptoms. From abstract, unclear what kinds of baseline differences existed between groups, and whether they were controlled for. ***Relates to discussion question #4***
B	10	Philippon et.al. reported professional hockey players who delayed surgery beyond one year after acute injury were significantly slower in returning to sport.[6] Patients without access to joint preservation surgery who have unremitting symptomatic FAI may be left with total hip replacement as the only next step alternative.	The citation was published before the date of the WA HTA report (last search date June 2011) (see comment #8).
B	11	**Diagnostic recognition.** The American Medical Association concluded FAI surgery was clinically effective and granted three Category Level 1 CPT codes effective January 2011.	See comment #2
B	12	The United Kingdom's National Institute for Health and Clinical Excellence (NICE) released guidance in September 2011 and July 2011, respectively, on arthroscopic and open surgery for FAI stating published evidence is adequate that surgery in symptomatic patients results in short- and medium-term benefits. [7,8]	See comment #5
B	13	Health technology appraisals from all national commercial insurers recommend coverage in patients	No TA available on the TEC website. Citation is a medical

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		with symptoms and documented inability to participate in desired activities. Regence Blue Cross/Blue Shield covering Oregon, completed and published a Health Technology Assessment of FAI surgery in February 2013 and recommends it as "medically necessary to debride the bone when specific criteria are met."[9]	coverage policy from BCBS, not a TA. Evidence review methods not specified and quality of review unknown. Evidence in the policy is summarized as follows: • Not all patients with FAI morphology will have FAI pathology. • There is a high association between FAI pathology and idiopathic osteoarthritis, but this may represent a small proportion of the total cases of hip osteoarthritis. • Patients may present with hip pain that can be diagnosed as FAI by a combination of clinical evaluation, radiographs, and MR arthrography. • In cases in which there is a positive impingement test result, anterosuperior labral or acetabular damage identified on MR arthrography and a pistol-grip morphology identified on imaging, there is a very high probability that the acetabular damage is caused by impingement of the femoral head-neck junction against the acetabular rim. FAI can be verified intraoperatively. • Repair of the labrum alone can improve symptoms in the short term. It is reasonable to expect that debridement/osteoplasty of the bump or bone spur would reduce continued abrasion in the long term. Some studies, albeit of low quality, support this view. • Treatment of FAI is most effective in younger patients without osteoarthritis (Tonnis grade 0 or I) or severe cartilage damage. Although osteoarthritis can be identified with plain film radiographs, articular damage is not always identified with current imaging techniques. • There is a high probability that symptoms in patients with osteoarthritis (Tonnis grade II or III, or joint space of less than 2 mm) or severe cartilage damage (Outerbridge grade IV) will not improve following osteoplasty. These patients may require THA for progressing pain within 5 years.

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			• In large case series, arthroscopic treatment of FAI in young to middle-age patients without osteoarthritis and showing mild to moderate cartilage damage results in 75% to 85% of patients improved. • Smaller case series suggest that open treatment of FAI in young to middle-age patients with moderate to severe cartilage damage results in 50% to 70% of patients improved. Non-union has been reported to occur in 27% of patients following the transection of the great trochanter with hip dislocation. The literature is uncertain with respect to the following: • It is not known whether arthroscopic or open approaches result in better net health outcomes when patients are matched for severity of FAI morphology and articular cartilage damage. • It is not known which patients with FAI morphology are most likely to progress to osteoarthritis. The progression of pincer impingement with damage initially restricted to the labrum may follow a different time course than cam-type impingement. • It is not known whether treatment of FAI will reduce the occurrence of osteoarthritis. HTAS has recommended coverage of surgical correction of FAI syndrome with medical necessity criteria. ***Relates to discussion question #6***
B	14	**Conservative management is ineffective.** A just published systematic review reports, "Outcomes of operative treatment of femoroacetabular impingement are significantly better than nonsurgical management."[10] Non-surgical treatment of symptomatic FAI does not provide permanent symptom relief, may require permanent lifestyle modification and fails to allow patients to return to desired activity levels. [6;11-28]	• Ref #10 (Harris 2013) is a SR that includes 29 studies, overall quality score was poor. All study types with a minimum 2 year FU were eligible for inclusion. 83% were case series, total N=2369. While the author reports statistics to support the superiority of operative over non-operative treatment, there was only one study of non-operative management, which was a case

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			series with n=37. No direct comparative evidence is reported. • Ref #6, 11-25 and 27 were published before the date of the WA HTA review (see comment #8). • Ref #26 is a case series of 23 patients evaluating the use of a specific hip distractor in the OR rather than a traction table. • Ref #28 is a retrospective case series of 47 high level athletes who underwent arthroscopic treatment of FAI. There was a 30% loss to follow up. The evaluable patients had significant improvements in pain (17/100 points) and function (12/100 points) scores (generally accepted minimum clinically important difference for HHS is 10). ***Relates to discussion question #2***
B	15	**Surgery relieves symptoms and allows patients to return to activity.** Over 46 peer-reviewed publications for symptomatic FAI using arthroscopic, open or a combination of these surgeries report patients' symptoms are relieved and the majority of patients are capable of returning to their previous level of activity.[6;11-13;15-21;23;26-62] *There are no unfavorable reports.* Arthroscopic surgery for FAI was associated with the lowest overall risk of complications. Among these publications, 21 reports with collectively over 1300 patients document favorable surgical outcomes in 75 to 100 percent of symptomatic FAI patients who had failed non-surgical management comprised of medication, reduced activity and physical therapy or rehabilitation programs lasting up to and over one-year. Typical patients have been able to return to recreational and work activities within months and professional athletes have had their careers extended.[6;11-15;17-23;26-28;45;53;55;58;61]	Minimum Clinically Important Difference (MCID) has not been defined according to the WA HTA report for either mHHS or NASH. • Refs #6-23, 27, 29-52 and 56 were published before the date of the WA HTA review (see comment #8). • For Ref #26 and 28, see comment #14. • Ref #53 is another case series of 200 athletes, median improvement in MHHS was 20 points. • Ref #54 is a retrospective cohort study comparing labral repair with labral resection, and reported more improvement in those undergoing labral repair. • Ref #55 is a case series of 100 treated arthroscopically, median improvement was 21 points. • Ref #57 is a case series of 120 treated with minimally invasive anterolateral approach. Mean improvement in non-arthritis hip score (NASH) was 32 points. • Ref #58 is a case series of 44 athletic patients treated with the mini-open approach. Mean HHS improved 24 points.

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			• Ref #59 is case series of 185/233 hips with 5 year FU treated with surgical hip dislocation. 82% were satisfied with the surgery. 14 hips underwent THA or major revision. • Ref #60 is SR that includes 31 studies of "generally low methodologic quality" and concludes "arthroscopy, open surgery and arthroscopic surgery followed by mini open surgery are comparable for functional results, biomechanics, and return to sport. Debridement and osteoplasty provide better results than debridement only. Significantly improved outcomes have been recorded in patients undergoing labral refixation than resection." • Ref #61 is case series of 60 patients < age 17. Mean improvement in MHHS was 34. 13% required a second surgery for adhesions. • Ref #62 is a case series of 153 patients > age 50. 20% required THA (time period not clear). HTAS has recommended coverage of surgical correction of FAI syndrome. ***Relates to discussion question #1***
B	16	Since 2008, seven independent systematic reviews of FAI surgery for symptomatic patients each concluded that published evidence support its safety and effectiveness.[10;63-68] Additional favorable reports have subsequently been published.[17;28;53;54;57-62]	• For Ref #10, see comment #14. • Ref #17 and 63-68 were published before the date of the WA HTA report (see comment #8). • For Refs #28, 53, 54 and 57-62, see comment #15.
B	17	**FAI surgery is reported to be cost-effective.** In a cost-effectiveness analysis[69] based upon best available data for patients with symptomatic FAI, observation or arthroscopic repair followed by hip replacement is compared to an endpoint of delaying total hip replacement surgery. FAI surgery was determined to be very cost-effective by the definition of cost-effectiveness used by the World Health Organization. It was more likely to demonstrate value in patients with limited pre-existing osteoarthritis or if progression to end-stage osteoarthritis is delayed.	Ref #69 is a CEA that reports an ICER of $21,700 assuming a 3 year benefit of arthroscopy and no impact of treatment on natural history (no delay of progression to OA). ***Relates to discussion question #5***
B	18	**FAI surgery is right for patients with unremitting symptomatic FAI.**	All referenced citations were published before the date of

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		FAI may be asymptomatic in many patients and all patients with FAI may not progress to osteoarthritis in the short-term. Additionally, outcomes are less favorable in the presence of preexisting advanced osteoarthritis of the affected hip.[6;11;20;29;30;46;70;71]	the WA HTA report (see comment #8).
B	19	HERC solicited orthopedic expert Dr. Andrea Herzka to review the evidence. She stated on the Expert Review Form submitted April 22, 2013, "…parameters for medical necessity must be established to allow this population to receive the current standard of care for FAI which is arthroscopic intervention." The strong recommendation your guidance proposes to not cover FAI surgery is contrary to the conclusions from the best available evidence, your expert reviewer, Medicare and commercial insurers. Failure to cover hip surgeries for FAI will prevent patients who are suffering from chronic pain and disability from access to a surgery unanimously found reasonable, safe, effective and medically necessary. Patients with unremitting pain from symptomatic FAI and no hip preservation surgery option may ultimately seek hip replacement, a more costly alternative. We urge you to act in the best interest of your patients and cover FAI surgery in symptomatic patients meeting appropriate criteria.	HTAS is aware of Dr. Herzka's opinion, as she has provided both oral and written testimony to the committee on two occasions. HTAS has recommended coverage of surgical correction of FAI syndrome.
C	20	The Arthroscopy Association of North America (AANA) is an Accredited Council for Continuing Medical Education approved organization which exists to promote, encourage, support and foster, through continuing medical education functions, the development and dissemination of knowledge in the discipline of surgery. This is done to improve upon the diagnosis and treatment of diseases and injuries of the musculoskeletal system to enhance the lives our patients. AANA has 3691 members across the United States, Canada and Mexico dedicated to this mission. We are recognized internationally as leaders in teaching the management of musculoskeletal disease states and have been using evidence based methodologies to support that teaching for over 30 years. We welcome the recent trend toward more evidence based practice that the Oregon Health Authority has adopted. AANA works closely with the American Academy of Orthopedic Surgeons in formulating Clinical Practice Guidelines and Appropriate Use Criteria to assist orthopedic surgeons in providing treatment recommendation that incorporate the best available evidence in the medical literature.	Thank you for your comment and your interest in evidence based practice.
C	21	The recent recommendation published for comment by the Health Technology Assessment Subcommittee (HTAS) of the Oregon State Health Evidence Review Commission (HERC) on the surgical treatment of femoroacetabular impingement (FAI) troubles us. We believe it violates the tenets of evidence based medicine and the currently recognized standard of care for patients with symptomatic FAI in the Oregon medical community as well as nationally. Evidence based medicine seeks to improve patient care by 1) using clinical expertise, 2) searching the scientific literature for the best available studies to evaluate and compare treatments, and 3)	Ref #1 also states "It is when asking questions about therapy that we should try to avoid the non-experimental approaches, since these routinely lead to false positive conclusions about efficacy. Because the randomized trial, and especially the systematic review of several randomized trials, is so much more likely to inform us and so much less likely to mislead us, it has become the "gold standard" for judging whether a treatment does more

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		include patient values and preferences in recommending therapies.[1] The HERC has severely limited the inclusion of all the medical evidence that supports the surgical treatment of FAI, discounted expert clinical opinion, and not included at all the aspect of patient preferences in its strong recommendation against coverage for these procedures.	good than harm." ***Relates to discussion question #1***
C	22	There are only two evidence sources cited for the recommendation; the Washington State Healthcare Authority Technology Assessment [2] and the National Institute for Health and Clinical Excellence (NICE)[3] both from 2011. The WSCH HTA severely circumscribed evidence synthesis rules to favor randomized clinical trials (RCT) as demonstration of procedure efficacy. This methodology ignores the over 40 peer-reviewed case-controlled and case series publications demonstrating improved outcomes from FAI surgery in symptomatic patients that this young, active population of patients experiences when conservative care fails. By stressing RCTs as the only measure of clinical efficacy, the HERC does not allow for a true assessment of the surgical literature as it exists today, limiting patient access to important therapies.	The WA HTA report is a full systematic review. It is unclear what the commenter means by "WSCH HTA severely circumscribed evidence synthesis rules to favor randomized clinical trials (RCT) as demonstration of procedure efficacy." The tenets of evidence-based medicine are clear that, in general, RCTs are required to draw valid conclusions, because to do otherwise results in significant propensity for bias. Indeed, nearly all Cochrane reviews limit their inclusion criteria to RCTs. However, given the large volume of studies with favorable results, and the likelihood of significant delay in conducting a RCT, HTAS has recommended coverage of surgical correction. ***Relates to discussion question #1***
C	23	The NICE report actually states, "Current evidence on the efficacy of femoro–acetabular surgery for hip impingement syndrome is adequate in terms of symptom relief in the short and medium term." [3] The NICE recommendation cited does not justify a strong recommendation against covering these procedures.	See comment #5 ***Relates to discussion question #1***
C	24	A recent high quality review of the surgical treatment of FAI not included in the HTAS review states, "Outcomes of operative treatment of femoroacetabular impingement are significantly better than nonsurgical management. Surgical treatment significantly improves outcomes, with no consistent significant differences exhibited between open and arthroscopic techniques. Open surgical dislocation has significantly greater reoperation and complication rates vs. mini-open and arthroscopic techniques. Outcomes of labral refixation are significantly better than debridement in patients with labral injuries."[4]	This is the same SR (Harris 2013) previously addressed in comment #14. ***Relates to discussion question #2*** ***Relates to discussion question #6***
C	25	As recognized experts in the treatment of these conditions, the members of AANA consider the surgical treatment of symptomatic FAI to be *the standard of care*[5] for those patients that fail the conservative management of these conditions. The HTAS recommendation against coverage violates this standard and places these patients at unnecessary risk of further pain, disability and potentially irreversible joint destruction.[6,7] Since FAI surgery is recognized as a standard, there is no clinical equipose[8] to support conducting RCTs. Indeed, "If the clinician knows, or has good reason to believe,	HTAS disagrees that there is no clinical equipoise, however, given the large volume of studies with favorable results, and the likelihood of significant delay in conducting a RCT, HTAS has recommended coverage of surgical correction.

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		that a new therapy (A) is better than another therapy (B), he cannot participate in a comparative trial of Therapy A versus Therapy B. Ethically, the clinician is obligated to give Therapy A to each new patient with a need for one of these therapies."[9]	***Relates to discussion question #3*** ***Relates to discussion question #4***
C	26	Lastly, Medicare and private insurers do cover surgery for FAI [10]. To deny coverage to patients for these procedures who are covered by Oregon State creates a potential treatment disparity for the poor and minority patients served by state programs such as Medicaid.	HTAS is aware of the coverage policies of other payers (see comment #3).
C	27	Evidence based methodologies are necessary to help improve patient care and make treatment more consistent with the current state of medical knowledge. It is important to have experts examine guidelines to offer necessary insight concerning their relevance and veracity. The members of AANA hope that you will reconsider your coverage decision to avoid the standard of care and treatment disparity issues we have described. We would be happy to advise the HERC on further guidelines concerning musculoskeletal healthcare to improve the care that all the citizens of Oregon deserve.	HTAS has recommended coverage of surgical correction of FAI syndrome.
D	28	The proposed draft for coverage for FAI is outdated and flawed. The literature used to create this draft comprised of articles published prior to 2011. More recent citations that I provided to the committee have not yet been incorporated into this guideline. Although the level of evidence of many outcome studies is level IV, their cumulative value is powerful. The safety and efficacy of hip arthroscopy for FAI associated non arthritic hip pain is well established.	None of the evidence previously submitted provides direct comparison between operative and non-operative management. However, given the large volume of studies with favorable results, and the likelihood of significant delay in conducting a RCT, HTAS has recommended coverage of surgical correction. ***Relates to discussion question #1***
D	29	A specific example of the inaccuracy of the proposed draft is the statement that there is no evidence to support one surgical treatment over another when Dr. Larson, Dr. Philippon and Dr. Ganz have both published that labral preservation results in significantly improved outcomes. As the expert on FAI for the state of Oregon, I cited several articles relevant to this guideline and published since the Washington State Health Care Authority Health Technology Assessment Program recommendation in early 2011.	Several cohort studies were provided previously that suggest differences in efficacy based on surgical technique, as reported in the Harris SR (see comment #14). The WA HTA report concludes the there is no evidence that one specific treatment, including surgical approach, results in better outcomes. HTAS does not believe the evidence is strong enough at the time to limit coverage of the procedure to one particular technique.
D	30	I provided a powerpoint presentation and strongly encouraged the subcommittee to create a category for medical necessity that would allow for coverage for this disabled patient population after failed conservative treatment and when all other criteria for medical necessity have been met. This is an effective way to allow disabled patients to have access to newer technologies when there are no known alternative treatment options.	HTAS has recommended coverage of surgical correction of FAI syndrome with medical necessity criteria. ***Relates to discussion question #6***
D	31	The authors also state that proponents of surgery for FAI "believe that surgical correction of the	Thank you for this clarification regarding the current

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		impinging deformities will alleviate the symptoms and retard the progression of osteoarthritis degeneration." This is incorrect. The current literature supports surgical intervention for patients with symptomatic FAI refractory to conservative treatment. The surgical goal is pain reduction and improved function. ***These*** outcomes measures have been successfully reproduced and documented in short and midterm outcome studies. The safety and efficacy of surgical intervention for FAI is very well documented. In patients with refractory non-arthritic hip pain due to FAI related chondrolabral care surgical intervention is the current standard of care. We are hopeful that long term data will *also* demonstrate a change in the natural history and retardation of arthritic progression, but at this time this data remains unknown. For this reason, FAI surgery is not indicated as a prophylactic surgery in individuals without significant disability and pain. The uncertainty of the natural history or the impact of surgery on arthritic progression is irrelevant to this guidance recommendation. This outcome measure can not be known for several years, but the efficacy of pain reduction and improved function and level of activity are outcome measures that are well documented in short and mid term outcome studies.	indications for surgical intervention.
D	32	**The algorithm used by the commission is incorrect. Under "alternative effective treatments available" the committee chooses "yes.'** **I am unaware of any alternative effective treatment options for FAI related non arthritic hip pain in patients refractory to conservative treatment.** My patients have all failed a combination of physical therapy, massage, steroid injections, acupuncture, chiropractic care, heat, ice, NSAIDS, and at times opiates prior to surgical intervention.	Thank you for providing your opinion on this matter. HTAS agrees that this service should be covered only for those who have failed all other treatment options. ***Relates to discussion question #2***
D	33	Nonarthritic hip pain associated with FAI can be debilitating. Many young patients are unable to walk, sit or perform their job duties. When conservative treatment fails in this patient population, surgical intervention becomes a matter of medical necessity. BCBS, aetna, Tricare, healthnet, lifewise, MODA, pacificsource, cigna, and providence insurance carriers have all updated their coverage guidelines for FAI based on the literature to cover surgery when "medical necessity" criteria are met. Although these criteria differ very slightly from one another, they are conceptually identical. The Washington State Health Care Authority Health Technology Assessment Program is the only group of reviewers to determine a non-coverage guideline and this was based on literature through the latter part of 2010. It is the only review to date that denies its patients of the current standard of care for the treatment of FAI.	HTAS is aware of the coverage policies of other payers (see comment #3). ***Relates to discussion question #4***
D	34	The data for FAI supports the following progression through the current HERC algorithm. **Alternative treatment avail?**- NO **Treatment risk compared to no treatment**- similar or less (difficult to quantify chronic pain and loss of function, weight gain due to inactivity and the cost of unemployment, obesity, depression and	*HTAS agrees and has changed its recommendation for coverage.* ***Relates to discussion question #3*** ***Relates to discussion question #4***

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		chronic pain) but the minor known risks of FAI surgery seem to outweigh the consequences of untreated pain **Treatment is prevalent**- YES – covered by all commercial insurance carriers and performed in every European country, Canada, Mexico, and Brazil, Korea, and Japan. **Clinical research study is reasonable**- NO	
D	35	Patients who have already failed months of PT and activity modification should not be subjected to further lack of intervention. The orthopedic surgery societies are all in agreement that denial of surgical intervention after failed conservative treatment is not ethical given the profound disability that these patients suffer.	HTAS has recommended coverage of surgical correction of FAI syndrome with medical necessity criteria. ***Relates to discussion question #3***
D	36	Certainly research to better understand the efficacy of conservative treatment of FAI is warranted. Those patients who have not trialed any conservative therapy should be studied, but unfortunately, this population might not be well represented in the orthopedic literature because the majority of patients who present to my office have already failed a course of PT and are desperate for pain relief. The primary care and/or physical therapy providers will likely need to conduct this type of study since they are likely treating patients with FAI associated pathology successfully with PT. Those patients rarely make it to my office and their exclusion creates a bias. In addition, patients successfully treated with PT often cancel follow up since they are improved. Finding a primary care practice with a high enough volume of FAI patients with hip pain to study prospectively is a huge hurdle to research. Capturing this patient population is extremely difficult and we will never know how many patients with mild pain self treat successfully with activity modification.	Thank you for clarifying that FAI can be treated conservatively with PT. HTAS has recommended coverage of surgical correction of FAI syndrome after failure of a trial of PT and other conservative management. ***Relates to discussion question #2*** ***Relates to discussion question #3***
D	37	Prospective evaluation of conservative treatment of FAI is challenging for the reasons explained above. For this reason, I have recommended that the subcommittee uses the algorithm to make a strong "yes" recommendation for the surgical treatment of FAI associated non arthritic hip pain in patients with symptoms refractory to conservative treatment. Those few patients whom I see in my office who have not trialed a formal course of PT with avoidance of flexion and focus on strengthening are treated initially with this conservative care. If treatment fails after 3-6 months, then surgery is recommended. It is my experience that a minority of patients are successfully managed without surgery, and that increased activity level/athleticism and younger age are associated with high failure rate of conservative care. Lastly, the subcommittee wanted to know how patients with this condition have been managed historically prior to this intervention. Many patients had to live with "a bum wheel." They could no longer go for a walk with friends, sit or stand at their jobs, or have sex without severe pain. These patients were often told "there was nothing wrong" because their X-rays did not demonstrate	Thank you for providing your opinion on this matter. HTAS has recommended coverage of surgical correction of FAI syndrome with medical necessity criteria. ***Relates to discussion question #2***

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		arthritis and nobody could explain this elusive groin pain. These patients lived with chronic pain and fear of hip rotation and flexion. Without an explanation for their pain they likely suffered both physically and emotionally.	
D	38	Dr. Ganz, the first surgeon to describe FAI came to this concept after performing hundreds of hip replacements in young patients with premature advanced arthritis and years of preceding pain with similarly misshapen hips. This finding guided his philosophy that this abnormal morphology caused painful injuries to the cartilage and labrum in the hip joint and led to eventual arthritis: thus, the introduction of the concept of FAI.	Thank you for this information.

References Provided by Commenters

A	None submitted
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D	None (references submitted previously)

Appendix A: Discussion Questions & Relevant Comments

(Used to guide discussion during 9/23/13 HTAS Meeting)

1. **Is the very low quality evidence sufficient to recommend coverage?**

   NICE and Washington HTA differed on the sufficiency of the evidence, with NICE finding it weak but sufficient for coverage with a registry. Many commenters believe case series evidence to be sufficient. See comments (4, 5, 15, 21, 22, 23, 28)

2. **Are alternative effective treatments available/accessible for persons with FAI?**

   Expert comment indicates physical therapy is sufficient for some (but not all) patients with FAI-related hip pain, but no evidence was reviewed regarding the effectiveness of physical therapy or other nonsurgical alternatives for those who do not benefit from physical therapy. See comments (14, 24, 32, 36, 37)

3. **Is conducting a higher-quality study reasonable despite prevalence of treatment?**

   Expert testimony is that a randomized trial is not reasonable due to prevalence of the treatment. See comments (25, 34, 35, 36)

4. **What is the risk compared to alternative/no treatment?**

   Commenters describe risk of significant disability for patients who fail to benefit from physical therapy and do not have FAI surgery. However, surgery includes some risk of complications. See comments (9, 25, 33, 34)

5. **How do cost, along with patient values and preferences, affect the subcommittee's decision after reviewing the evidence?**

   Commenters cite the disabling nature of this condition, and its effects on younger patients which could result in high costs to society and patient preference for surgery. See comments (17)

6. **If the subcommittee chooses to recommend coverage, what are the appropriate indications for surgery? Should the subcommittee recommend coverage for resection and repair, or just repair?**

   See comments (13, 24, 29)

7. **Comments Designated for HTAS Discussion**

   See comments (6, 13, 15, 19, 21, 27, 30, 31, 32, 34, 37)