

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

## General Comments

Stakeholder	#	Comment	Disposition
Smith & Nephew, Inc. Andover, MA	1	Smith & Nephew, Inc. is a global medical technology business specializing in Endoscopy, Orthopedics and Wound Management. We comment on the no coverage recommendation based on the flawed 2011 Washington State FAI review for hip surgeries for Femoroacetabular Impingement (FAI). Focus on the lack of definitive evidence that FAI surgery alters the course of osteoarthritis is shortsighted.	<i>Final Coverage Guidance deferred</i>
	2	Non-surgical treatment of symptomatic FAI is widely acknowledged <sup>1-19</sup> to: <ul style="list-style-type: none"> <li>• not provide permanent symptom relief;</li> <li>• require lifestyle modification;</li> <li>• and, fail to allow patients to return to desired activity levels.</li> </ul>	The non-surgical treatment of FAI was not included in the scope of this review or addressed in this coverage guidance document.
	3	Failure to cover hip surgery for FAI despite the fact that medically- and cost-effective <sup>20</sup> surgery is available should concern affected constituents who may find permanent activity reduction and possibly sustained hip pain and disability unacceptable.	Ref #20 is a cost-effectiveness analysis that employed a number of assumptions about disease progression and efficacy of hip arthroscopy that are not well-established based on the WA HTA evidence review.
	4	The American Medical Association concluded FAI surgery was clinically effective granting three Category Level 1 CPT codes effective January 2011. Criteria for such includes “that the clinical efficacy of the service/procedure is well established and documented in U.S. peer review literature.”	The existence of a Level 1 CPT code is not sufficient evidence of effectiveness.
	5	All national U.S. commercial insurers cover FAI surgery because their publically available health technology appraisals determined that FAI surgery helps patients with symptoms and documented inability to participate in desired activities.	The EbGS is aware of this, but does not reach its conclusions based on the decisions of other payers.
	6	The United Kingdom’s National Institute for Clinical Excellence released guidance in September <u>2011</u> and July <u>2011</u> , 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.	<i>Final Coverage Guidance deferred</i>
	7	Since 2008, six independent systematic reviews of FAI surgery for symptomatic patients each concludes that published evidence support its safety and effectiveness. <sup>21-26</sup> Additional favorable reports have subsequently been published. <sup>7, 19, 27-34</sup> There are no unfavorable reports.	Refs #7, 21-26 were all published before the date of the WA HTA evidence review (last search date June 2011). See comment #2 regarding ref #19. Ref #27 is a case series, N=200, 19 month follow up, arthroscopy. Ref # 28 is an uninterrupted prospective case series, N=120, 1 year follow up, minimally invasive approach. Ref #29 is case series, N=44, athletes, mini-open approach, 1 year

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			<p>FU.</p> <p>Ref #30 is retrospective case series, N=184, open approach, follow up 2-10 years.</p> <p>Ref #31 is a review that compared outcomes based on approach. Included 31 studies, concluded that all three approaches are comparable for functional results, biomechanics and return to sport, but that open and mini-open approaches are contraindicated in patients with severe OA.</p> <p>Ref #32 is prospective, consecutive case series, N=60, ages 11-16, arthroscopic approach, FU 2 years.</p> <p>Ref #33 is prospective, consecutive case series, N=153, age &gt;50, arthroscopic approach, FU 1-3 years.</p> <p>Ref #34 compared patients with FAI and labral tears treated with either labral resection or labral repair.</p>
	8	<p>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.<sup>1-3, 5-11, 13, 14, 17-19, 27-60</sup></p> <p>Arthroscopic surgery for FAI was associated with the lowest overall risk of complications.</p>	<p>Refs #35-58 and 60 were published before the date of the WA HTA evidence review (last search date June 2011). The EbGS 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 EbGS does not investigate individual studies published before the date of the review. The EbGS 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.</p> <p>Ref #59 is a consecutive prospective case series, N=100, 2 year FU, arthroscopic approach.</p>
	9	<p>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.<sup>1-5, 7-14, 17-19, 27, 29, 32, 51, 59</sup></p>	<p>There are no RCTS of surgery for FAI compared to conservative care, or comparing different surgical treatments for FAI.</p>

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	10	A cost-effectiveness analysis <sup>20</sup> of FAI surgery compared to observation for patients with symptomatic FAI, with an endpoint of delaying total hip replacement surgery, found FAI surgery to be very cost-effective according to the definition of cost-effectiveness used by the World Health Organization.	See comment #3 regarding Ref #20.
	11	Failure to cover hip surgeries for FAI will prevent patients who are suffering from chronic pain and lifestyle altering disability from having access to surgeries found, by near unanimous preponderance of best available peer-reviewed evidence, reasonable, safe, effective and medically necessary. We urge you to act in the best interest of your patients and reverse the no coverage recommendation.	This evidence base includes only one retrospective study comparing surgery vs. conservative care, and 4 retrospective studies comparing various surgical treatments for FAI. Per the authors of the WA HTA, “The results of these studies should be taken with caution. The fact that these studies (1) are retrospective cohorts mostly using historical controls, (2) did not clearly account for all excluded patients, and (3) only included patients who completed follow-up or who had complete clinical and radiographic data creates the potential for selection, performance and attrition bias. Selection bias is an inherent problem with cohort studies since systematic differences arise from self selection or physician-directed selection of treatments. In these cases, selecting patients for inclusion based on the completeness of the data in one’s database is likely to produce a subset of patients that are different than patients not in the database but who received the treatment of interest. Performance bias in these studies is a real possibility due to the use of historical controls. For example, differences in the level and competency of care may exist between historical controls and those treated with more current and improved surgical methods or by surgeons who have acquired more experience over time. Finally, attrition bias can result when those who do not return for final follow-up are systematically different from those who remain in the study, thus changing the overall group characteristic in a way that is unable to be controlled or accounted for.” The remainder of the evidence base consists of case series.
<i>Oregon Association of Orthopaedists, Inc.</i>	12	Our members are medical and osteopathic physicians specializing in orthopaedics and practicing throughout Oregon. I want to express our objection to the above-referenced Coverage Guidance.  We urge the Commission to consider the fact that since 2008, six independent systematic reviews of FAI surgery have concluded that published evidence supports	Thank you for your comment. Please see response to comments #7 and #11.

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Portland, OR		<p>its safety and effectiveness. More than forty peer-reviewed publications for symptomatic FAI using arthroscopic, open, or a combination of these surgeries report that patients' symptoms are relieved and they are able to return to work and other activities. We urge the Commission to hold a hearing and review this information. We believe that evidence clearly shows that surgical treatment of FAI can in fact provide long-lasting relief from pain and be cost-effective by reducing or eliminating a patient's need for costly pain relieving medication.</p> <p>We urge the Commission to re-consider the proposed Coverage Guidance on Hip Surgical Procedures for FAI, so that these procedures can remain an option for Oregon patients.</p> <p>Thank you for your consideration of our objections.</p>	
<i>American Association of Orthopaedic Surgeons</i> Washington, D.C.	13	<p>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 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. I currently serve as the President of the AAOS and have practiced in Tualatin, Oregon for more than 30 years.</p>	Thank you for this information.
	14	<p>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 because we do not believe this decision is consistent with evidence showing that hip arthroscopy is a cost-effective treatment for the management of FAI Syndrome. Surgical treatment of FAI can provide long-lasting symptom relief and allows patients to return to work or other desired activities without lifestyle modification.</p>	Thank you for your comment. Please see response to comment #11.
	15	<p>The American Medical Association 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 by claiming that they are experimental or investigational. When payers do otherwise, they</p>	Please see response to comment #4.

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		threaten the health of the public and unjustifiably interfere with the physician/patient relationship.	
	16	All national U.S. commercial insurers cover FAI surgery because it has been shown to be clinically effective. This includes Aetna, which the Washington Health Technology Assessment claims does not cover FAI surgery. Aetna’s current health technology appraisal not only recommends coverage of FAI procedures, but also cites the Washington HTA as the only study among dozens that recommends against its clinical effectiveness.	The EbGS appreciates you alerting us that the WA HTA report is erroneous in its claims about Aetna coverage policy. Please see response to comment #5.
	17	Since 2008, six independent systematic reviews of FAI surgery have concluded that published evidence supports its safety and effectiveness. More than 40 peer-reviewed publications for symptomatic FAI using arthroscopic, open, or a combination of these surgeries report that patients’ symptoms are relieved and they are able to return to their normal activity levels.	The primary evidence base for this topic consists almost exclusively of case series. Systematic reviews of low quality studies do not provide strong evidence of efficacy or effectiveness. Please see response to comment #11.
	18	The AAOS urges the Committee to revise its coverage guidance on hip surgery procedures for Femoroacetabular Impingement Syndrome to be consistent with the vast majority of other 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.	<i>Final Coverage Guidance deferred</i>