

WASHINGTON STATE HEALTH CARE AUTHORITY

Peer Review, Public and Washington State Agency Comments and Responses for FAI

Health Technology Assessment

Friday, August 26, 2011

Health Technology Assessment Program

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1. RESPONSE TO PUBLIC COMMENTS

A. Dr. Carlos Guanche

Comment 1

A more effective analysis would be to break down the literature further in an attempt to document the effectiveness of treating cam, pincer and mixed combinations of hip problems. The analysts involved in your assessment do not appear to have the in-depth knowledge for this type of study and I would submit to you that this is another failing of your analysis.

Response 1:

The data were not available to evaluate the comparative effectiveness of FAI treatment for cam, pincer and mixed combinations of hip problems.

Comment 2:

The broad inclusion of surgical treatments for hip pathologies without regards to arthroscopic surgery versus open is concerning. Just one aspect of this broad analysis confuses the issue of complications.

Response 2:

We stratified all outcomes by surgical type, i.e. Arthroscopic, Open, Mini-Open, (see Tables 9, 10 & 11 of the report). However, it must be remembered that these are case series and comparison of results among surgical procedures using these studies is tenuous.

Comment 3:

...the one case that is quoted as being one of abdominal extravasation is one where there was an acetabular fracture, not a case of FAI.

Response 3:

The author of the study states: “We report an occurrence of extravasation of fluid into the abdomen during arthroscopic treatment of femoroacetabular impingement and our management of the condition postoperatively.” The pelvic fracture was an old injury which may have contributed to the abnormal morphology. However, the author states that “surgeons should be aware of fluid extravasation as a complication of any arthroscopic procedure.”

Comment 4:

...serious concerns with the use of the Tönnis score as a correlation to outcomes studies. The score was developed to document the degree of arthritis in a hip joint and has never been correlated with any patient outcomes, either in any study or by the developer of the score.

Response 4:

The Tönnis score was used in some studies to limit the study population or to document the baseline arthritis status prior to surgery. We documented the studies that stratified the results based on the level of arthritis estimated from the Tönnis score.

Comment 5:

In all of the current studies, including four that were not included (Ilizaliturri, Byrd, Philippon, Brunner), when the degree of Tönnis arthritis is 1 or less, the outcomes are excellent.

Response 5:

These studies were included in the report. The data abstracted from each are found in Appendix G.

B. Smith & Nephew (comments were sent in 3 flavors: general overview, specific comments by Key Questions and specific comments by page of the draft HTA. The following response will follow the comments as listed by the Key Questions.

Key Question 1, comments 1-6

(See attached PDF from Smith & Nephew)

Response KQ1, comments 1-3:

KQ1 asks whether there is consistent or agreed upon case definition for FAI, and what is the evidence of reliability and validity of these case definitions?

To answer the first part of this question, a consistent or agreed upon case definition, we identified the inclusion and exclusion criteria of prospective studies of therapy in patients scheduled to have FAI surgery. Inclusion/exclusion criteria of clinical trials were used because these criteria define a subpopulation of patients thought to have the condition. Prospective was chosen because retrospective studies only have available those criteria that were collected at baseline while prospective studies are able to state up front all the criteria that best identifies the FAI population. One way to assess whether there is an agreed upon case definition for FAI is to compare these criteria. Unfortunately, there are very few prospective studies that state these criteria *a priori*.

With respect to reliability and validity, studies that identified FAI from surgical inspection and looked at the diagnostic criteria used to predict the diagnosis were included.

KQ1 response to comments 4-5. The commenter fails to divide the KQ into the two components, (1) Is there a consistent or agreed upon case definition, and (2) What is the reliability/validity of these definitions. The commenter states that “among the three prospective trials used to reach a conclusive claim that ‘there is no evidence that the diagnosis of FAI can be obtained from clinical exam’, two were inappropriately reported as lacking sufficient non-invasive documentation justifying patient inclusion”. The references to which the commenter cites (Horisberger et al and Philippon et al) were not

used to make this statement. Rather, this was concluded after looking at the diagnostic accuracy of the clinical exam (Martin et al) and the alpha angle and impingement test (Lohan et al). Table 6 in the report summarizes the diagnostic accuracy of these reports and forms the basis of the conclusion.

KQ1 response to comment 6. The commenter identifies 2 prospective studies that we concluded did not state inclusion/exclusion criteria. One was Gedouin et al who state that surgery was indicated for disabling symptomatology of more than 6 months' duration and presented with clinical and radiological signs of impingement. The authors do not state which clinical tests needed to be present for inclusion. They describe 2 radiographic assessments, one for CAM (alpha angle >50 degrees), and one for pincer (positive crossover sign). There is no indication that one or the other must be present as opposed to other radiographic criteria (e.g. they state that some of their patients had coxa profunda or protusion.)

The second study by Stahelin also lacks explicit inclusion criteria. However, they state that all symptomatic FAI cam impingement were included, and given that all patients had "impingement" (presumably a positive impingement test) and all had an alpha angle of 50 degrees or more, we have included this study in the final draft.

We agree with the comment about the inconsistent assessment on Jaeger et al (we judge it to be a retrospective study), and the report was edited in KQ1 to reflect this. Pierannunzii et al is unclear. Since the authors state that the study is ongoing, we judged it to be prospective.

KQ2 response to comment 2

One of the goals of FAI surgery is to delay or prevent hip OA. One way to determine OA progression is to evaluate the Tonnis grade before and after surgery. Since the Tonnis grade is used by some authors to determine if hip OA progresses (Bardakos 2009, Clohisy 2010 "combined", Espinosa 06, Gedouin 2010 update, Lincoln 2009) we evaluated whether there were valid or reliable studies of this measure.

KQ2 response to comment 4

We agree with the commenter that these are confusing. We edited the text to say "Of these, two outcome measures have been tested for validity in FAI patients . . ."

KQ3 response to comment 1

Efficacy is defined as evidence from randomized controlled trials. To make this clearer, we added the following sentence to the report under 4.3.1. "We considered randomized controlled trials as providing evidence on efficacy."

KQ3 response to comment 2

It is not known what exactly contributes to the results from most (if not all) case series. We state some of the obvious potential contributors. It takes better study design to control for these factors in order to attribute results to the intervention.

KQ3 response to comment 4

The point that one Level of Evidence IV study (case series of a small conservatively treated group of patients) had mild FAI and may not be similar with respect to the population that undergoes surgery is well taken. We edited our report to emphasize this point.

KQ3 response to comment 5

While there is logic to the idea that impingement leads to labral damage, therefore repair (or debridement) of the labrum without correcting impingement will lead to failure, the results demonstrating this in FAI patients are lacking. There are two poorly done cohort studies (using historical controls) of small sample size and short follow-up on this topic. Neither demonstrated convincing evidence that osteoplasty (in the short term) resulted in better outcomes (Table 9).

KQ3 response to comment 6

Two authors asked the question whether preservation of the labrum (refixation) vs. debridement would lead to improved outcomes in patients receiving arthroscopic treatment of FAI. Again, these were two retrospective studies with poor quality, and we reported their findings in Table 9.

KQ4 response to comment 1 and 2

We present risks of adverse events/complications stratified by procedure (arthroscopy, open, and mini-open), Table 11. Since these are case-series, care needs to be taken with respect to inferences comparing risks between surgical procedures. As the commenter implies, there are other factors that were not accounted for that could contribute to risks. With respect to combining risks within strata, those wishing to see risks by individual study can find those in the detailed tables, Appendix H.

KQ5 response to comment 1

Key question 5 pertains to differential efficacy. By definition, this requires at least two different treatments and at least two different exposures (patient characteristics). A discussion of whether these case-series are “one-way crossover” trials is mute for this question.

2. Response to WA State Agency Comments

Agency comment	SRI Response
<p>1. Summary to Key Q2 (p 74) does not address the question completely. Addresses questions about measures but not treatment goals.</p>	<p>1. The goals of FAI surgery are to reduce pain and increase function/activity, and delay or prevent hip osteoarthritis. The common outcome measures to assess the former were identified in Fig 2. The only outcome measure we found to assess the latter goal was the progression of osteoarthritis as determined by the Tönnis scale.</p>
<p>2. Summary to Key Q3: no efficacy data. 3 bullets on short-term effectiveness but no summary of the overall quality of this evidence here (p 89), mention of ‘case-series’. May be helpful to note the overall quality of the evidence available for short and long-term effectiveness in the summary.</p>	<p>2. The summary to key questions is found in the strength of evidence tables on page 101. We edited the text on p89 to be consistent.</p>

3. Response to Clinical Reviewers

We did not receive any responses from the clinical reviewers by the close of the comment period. Dr. John Green submitted his clinical review after the comment period, and it is included below.

Clinical Reviewer: John R. Green, III MD

INTRODUCTION Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Overview of topic is adequate? Yes
- Topic of assessment is important to address? Yes
- Public policy and clinical relevance are well defined? Yes

BACKGROUND Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Content of literature review/background is sufficient? Yes

REPORT OBJECTIVES & KEY QUESTIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Aims/objectives clearly address relevant policy and clinical issue? Yes
- Key questions clearly defined and adequate for achieving aims? Yes

METHODS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Method for identifying relevant studies is adequate? Yes
- Criteria for the inclusion and exclusion of studies is appropriate? Yes
- Method for Level of Evidence (LoE) rating is appropriate and clearly explained? Yes
- Data abstraction and analysis/review are adequate? Yes

RESULTS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Amount of detail presented in the results section appropriate? Yes
- Key questions are answered? Yes
- Figures, tables and appendices clear and easy to read? Yes
- Implications of the major findings clearly stated? Yes
- Have gaps in the literature been dealt with adequately? Yes
- Recommendations address limitations of literature? Yes

CONCLUSIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Are the conclusions reached valid? Yes

This is a difficult clinical problem that we are still early in our understanding. I find the most useful clinical test is a diagnostic injection. Although there is a single report of reasonable success with non-operative treatment; I've not had much success with that. There are multiple reports of short term benefits with surgical management. This is a spectrum of disease and therefore, there are multiple ways to treat the bony and labral pathology. My patients have gotten considerable benefit from arthroscopic hip surgery. As our understanding evolves, we will be able to answer these questions with more scientific certainty.

OVERALL PRESENTATION and RELEVANCY Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Is the review well structured and organized? Yes
- Are the main points clearly presented? Yes
- Is it relevant to clinical medicine? Yes
- Is it important for public policy or public health? Yes

QUALITY OF REPORT

Quality of the Report

(Click in the gray box to make your selection)

Superior

Good

Fair

Poor

ORTHOPEDIC SURGERY

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August 16, 2011

Leah Hole-Curry, JD
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Dear Ms. Hole-Curry,

As a practicing orthopaedic surgeon, who specializes in the treatment of hip pathology, has written a textbook on hip arthroscopy and frequently performs the procedures, I appreciate the opportunity to comment on the subject of Femoroacetabular Impingement (FAI). I have personally analyzed the available literature and would like to offer my conclusions. I believe the exclusion of practicing surgeons with expertise in this area from the analysis may deny significant insight to the pathology and the surgical solution. Perhaps a greater effort could have been made to assure that the assessment was broadly based and developed by consensus. In summary, the preponderance of evidence is positive with regards to the arthroscopic treatment of hip problems and I would like to briefly review a few of these points.

First of all, the arthroscopic treatment of Femoroacetabular Impingement (FAI) has been shown to be medically necessary and reasonable as demonstrated by the American Medical Association (AMA) in their development of a level I CPT code (actually three codes) for the treatment

of FAI. The acceptance of a specific Level I CPT code is predicated on the uniqueness of a procedure, its performance by many physicians nationally, as well as accepted outcomes and clinical improvements that have been documented in the peer-reviewed literature. The body that reviews and accepts or denies these codes, The Editorial Panel of the American Medical Association (AMA) is made up of multiple practicing physicians with a broad fund of clinical expertise in the actual treatment of patients.

The idea that there are three separate codes for the surgical procedures associated with this spectrum of pathologies also speaks to your first question, with regards to the definition of FAI. This is not one disease, but a variety of morphological variations about the hip socket including abnormalities at the head and neck junction as well as variations in the shape and orientation of the acetabulum. A more effective analysis would be to break down the literature further in an attempt to document the effectiveness of treating cam, pincer and mixed combinations of hip problems. The analysts involved in your assessment do not appear to have the in-depth knowledge for this type of study and I would submit to you that this is another failing of your analysis.

In addition, an overwhelming number of U.S. insurance providers (with only one notable exception) have made coverage decision in favor of FAI. This is clearly documented in the Washington State Health Care Authority (WSHCA) document, Table 3. According to these insurers and their clinically based panels, there is sufficient, compelling evidence that patients receive short and medium term benefit from the procedures directed at treating FAI.

In reviewing these policies, the majority of insurers require a period of three to six months of non-surgical management of these patients. In the absence of improvement of their symptoms, they feel it is reasonable to proceed with surgery. This would appear to be a trial of non-surgical treatment that is reasonable and ethical. The request by the Washington panel for a series of symptomatic patients to be treated non-surgically for an extended period would pose a significant ethical dilemma for a practice

surgeon who is well apprised of the surgical literature. There is little likelihood of obtaining approval from an Institutional Review Board for that study based on the potential risk and irreversible changes for the progressive effects of FAI.

The broad inclusion of surgical treatments for hip pathologies without regards to arthroscopic surgery versus open is concerning. Just one aspect of this broad analysis confuses the issue of complications. While the raw number of percentage of complications in patients undergoing arthroscopic versus open FAI surgery may be similar, the reality is that approximately 95% of the complications that have been attributed to the arthroscopic approach have been transient nerve palsies of either the pudendal or lateral femoral cutaneous nerves, of which less than 1% have led to any permanent problem. In addition, the one case that is quoted as being one of abdominal extravasation is one where there was an acetabular fracture, not a case of FAI.

I also have serious concerns with the use of the Tönnis score as a correlation to outcomes studies. The score was developed to document the degree of arthritis in a hip joint and has never been correlated with any patient outcomes, either in any study or by the developer of the score.

Another point is that the preponderance of evidence for the effectiveness of FAI surgery is positive.

While much evidence is of quality frequently graded low by virtue of the lack of prospective randomized trials, clinical outcome results are virtually all directionally similar indicating a favorable response to surgery. In none of the quoted studies has there been a negative trend in the response to arthroscopic intervention. Clearly, some of the earlier studies, where the degree of arthritis was not documented, indicate a higher failure rate than most of the more contemporary studies, such as the Larson and Giveans study that you quote. In all of the current studies, including four that were not included (Ilizaliturri, Byrd, Philippon, Brunner), when the degree of Tönnis arthritis is I or less, the outcomes are excellent. Essentially, there is no literature to support not treating the problem!

Additionally, your cost analysis portion completely ignores the preponderance of evidence that essentially any arthroscopic procedure is less expensive, less likely to cause a complication and overall better tolerated and accepted by patients. Overall, outcomes inclusive of complication rate and potential economic advantages clearly and emphatically favor arthroscopic surgery. This is an accepted tenet of orthopedic surgery and is confirmed with the arthroscopic treatment of FAI.

This information represents the opinions of the Arthroscopy Association of North America (AANA) and a passionate surgeon concerned for the well-being of his patients. Denying coverage to patients suffering the pain and limitations imposed by femoroacetabular impingement is unnecessary and saddening. I hope you will consider coverage of this cost effective and highly successful intervention for you constituents.

References

- Ilizaliturri VM, Jr., Orozco-Rodriguez L, Acosta-Rodriguez E, Camacho-Galindo J. Arthroscopic treatment of cam-type femoroacetabular impingement: preliminary report at 2 years minimum follow-up. *J Arthroplasty* 2008;23(2):226-234.
- Byrd JW, Jones KS. Arthroscopic femoroplasty in the management of cam-type femoroacetabular impingement. *Clin Orthop Relat Res* 2009;467(3):739-746.
- Philippon MJ, Briggs KK, Yen YM, Kuppersmith DA. Outcomes following hip arthroscopy for femoroacetabular impingement with associated chondrolabral dysfunction: minimum two-year follow-up. *J Bone Joint Surg Br* 2009;91(1):16-23.
- Brunner A, Horisberger M, Herzog RF. Sports and recreation activity of patients with femoroacetabular impingement before and after arthroscopic osteoplasty. *Am J Sports Med* 2009;37(5):917-922.

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VIA E-MAIL

August 17, 2011

Dear Ms. Hole-Curry:

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

We appreciate that the Washington State Health Care Authority Health Technology Assessment Program has invited comments on the draft Health Technology Assessment (HTA) on Hip Surgery Procedures for Treatment of Femoroacetabular Impingement Syndrome conducted by Spectrum Research, Inc.

Our comments are attached in four parts:

1. A general overview commenting on the Draft HTA content. (page 2)
2. Appendix A. Specific Comments by the Key Questions identified in the Draft HTA. (page 3)
3. Appendix B. Specific Comments by page of the Draft HTA. (page 10)
4. Appendix C. Documentation of FAI surgery coverage policy by U.S. medical insurers. (page 23)

We acknowledge the medical review of these comments by:

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Please contact us should additional clarification be required.

Sincerely,

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COMMENTS on WA State HCA Draft HTA for Treatment of FAI Syndrome

GENERAL COMMENTS:

1. The Health Technology Appraisal (HTA) of Hip Surgery Procedures for Femoroacetabular Impingement (FAI) Syndrome commissioned by the Washington State Health Care Authority (HCA) improperly concludes that there is no data available proving the short- and mid-term effectiveness of FAI surgery is superior to that of no surgery, contains numerous factual or interpretative errors, including but not limited to: incorrectly identifying isolated repair of labral pathology as correction for FAI, inaccurately assessing case series describing clinical outcomes, and inappropriately elevating the value of a 37 patient Egyptian report describing non-surgical treatment of "mild" FAI. Overall it fails to reasonably integrate the body of literature into an objective appraisal of medical and humanistic outcomes related to surgical repair of visually documented FAI in patients presenting with disabling symptoms. (Documentation in Appendices A and B)
2. The principal point seemingly not recognized by the draft report is that all peer-reviewed published reports of outcomes from surgery to repair symptomatic FAI, whether prospective or retrospective, initiate from patients absolutely known to have FAI pathology on visual inspection during surgery.
3. The issue of correct non-invasive diagnosis of patients evaluated for FAI as the etiology of their presenting symptoms is different from the issues of whether surgical repair of symptomatic FAI as documented intra-operatively was reasonable, medically necessary, safe and effective in resolving the presenting symptoms and allowing the patient to return to pre-injury levels of activity.
4. The draft report improperly changed the Key Questions 3, 4, 5, and 6 from those Final Key Questions published on the WA HCA website, to require comparison to non-surgical treatment.
5. The draft report fails to inform that 239 million patient lives in the United States are covered for FAI surgery following review of the procedure by respective appraisal processes within the various private medical insurance providers, excepting one national provider. (See Appendix C)
6. The draft report fails to inform that three level 1 CPT Codes for FAI were introduced in 2011. These are CPT Code 29914 (Arthroscopy, hip, surgical; with femoroplasty (i.e., treatment of cam lesion); CPT Code 29915 (Arthroscopy, hip, surgical; with acetabuloplasty (i.e., treatment of pincer lesion); and, CPT Code 29916 (Arthroscopy, hip, surgical; with labral repair).
7. The draft report does not reflect the fact that the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom updated its guidance on FAI surgery in July 2011 finding that evidence was "adequate in terms of symptom relief in the short and medium term."
8. The conclusions of the Spectrum HTA of surgery for FAI are in direct contradiction to the independent conclusions of five systematic reviews of FAI published in the peer-reviewed literature between 2008 and early 2011.
9. Some may raise concern about the objectivity and scientific integrity of a health technology appraisal focused on questioning the diagnostic judgment of medical and surgical practitioners rather than assessing if: (1) the treatment applied is appropriate for the diagnosis defined; (2) the appropriate treatment alternatives for the diagnosis are each safe and effective; (3) there are clinically meaningful differences in medical, humanistic or economic outcomes between the defined equivalent alternatives; and, (4) the treatment is medically necessary and reasonable. It is this last evaluation that is generally considered most appropriate for medical coverage decisions.

COMMENTS on WA State HCA Draft HTA for Treatment of FAI Syndrome

APPENDIX A.

Comments By Key Question

Key Question 1	<ol style="list-style-type: none"><li data-bbox="470 367 1404 462">1. It is inappropriate to exclude or dismiss peer-reviewed literature reporting outcomes from patients receiving surgical intervention for symptomatic FAI due to inadequate description of pre-surgical assessments. Spectrum's assessment of the reliability and validity of the "case definitions" for the literature reporting clinical outcomes from surgery to correct FAI is questionable. They concluded that in the majority of the peer-reviewed literature, non-invasive pre-surgical clinical and radiologic assessments insufficiently identify patients as having the pathology clearly identified during surgery. We agree that when prospectively establishing a patient's diagnosis, the diagnostic reliability and validity of non-invasive assessments, e.g. clinical observation, laboratory tests and radiologic assessments, must correctly identify the actual pathology. The point of such assessments is how well they accurately predict the presence of the pathology the diagnosis reflects. However, the issue in the peer-reviewed literature of surgery for symptomatic FAI is different. The outcome reports start with the pathology being known from direct visualization during surgery. Many reports are actually retrospective analyses of prospectively collected data. The point of evaluating the predictive reliability and validity of diagnostic assessments is that they correctly identify the pathology behind the symptoms leading a patient to seek medical care. In the reviewed outcome reports, the diagnosis was definitive.<li data-bbox="470 1102 1404 1333">2. An inappropriate assessment bias against the reference standard of a visual diagnosis (draft report pages 9, 46) is demonstrated within the draft report. Discounting the validity of published peer-reviewed clinical outcome trials because of a potential lack of alignment between incidentally described pre-operative non-invasive clinical and radiographic assessments and the actual intra-operative visual diagnosis fails to demonstrate thoughtful consideration of the works. It appears disingenuous to focus the literature review and appraisal on finding a statement indicating that pre-operative assessment was confirmed by the intra-operative diagnosis. Rather, confirmation of the presence of FAI intra-operatively should have been the principal criterion defining the appropriateness of including any given peer-reviewed published outcome trial in the assessment. This is further relevant applied to answering Key Question 3.<li data-bbox="470 1585 1404 1648">3. Clinical interpretations of included and <u>excluded</u> reports that impact this assessment were flawed in many areas.<li data-bbox="470 1680 1404 1837">4. The draft report claimed only three trials were prospective and had adequate case definition by non-invasive assessment. However, one of these trials¹ was designed to evaluate an ancillary technology rather than the clinical outcome of the FAI surgery or the correspondence between pre-operative diagnosis and intra-operative pathology so should not have been used.
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COMMENTS on WA State HCA Draft HTA for Treatment of FAI Syndrome

	<p>5. Among the three prospective trials used to reach a conclusive claim that “there is no evidence that the diagnosis of FAI can be obtained from clinical exam”, two were inappropriately reported as lacking sufficient non-invasive documentation justifying patient inclusion.^{2,3}</p> <p>6. Among the claimed five trials that appeared prospective but were excluded because they were said not to have stated patient inclusion criteria, two did identify inclusion criteria on close inspection.^{4,5} Of the remaining three, two were not prospective.^{6,7} Demonstrating the inconsistency of the draft report, one of these, identified as “appears prospective” on page 47 of the draft report, is called a “retrospective cohort” study on page 76 of the draft report.⁶ The last of these three evaluated Egyptian patients with “mild FAI” defined by excluding patients with “major bony pathology” and managed non-operatively. Such patients are not comparable to those included in Western trials.⁸</p>
Key question 2	<p>1. The response to this question demonstrates inconsistency and questionable interpretation of the literature.</p> <p>2. The response suggests that the Tonnis grading system measures the outcome of FAI surgery relative to progression to or avoidance of osteoarthritis. The Tonnis grading system is a well-recognized and widely applied classification system for the severity of hip dysplasia found on diagnostic radiographs.</p> <p>The draft report goes so far as to say, “We found no study that sought to validate the Tonnis classification for hip arthritis.” Such assessment is beyond the scope of the commissioning and irrelevant to the defined assessment.</p> <p>3. It is interesting that construct validity of evaluated outcomes instruments was assessed against non-invasive diagnostic elements reported within the draft report as poorly diagnostic of FAI.</p> <p>4. We have difficulty reconciling the statement on page 60, “Of these, two outcome measures have been validated in FAI patients: HOS-D and M-WOMAC (12).” with the summary conclusions on page 74 that “only one (NAHS) of the three instruments was adequately tested for validity, and it was performed in a young hip-pain patient population. Content validity was inadequate for the other two (HOS, M-WOMAC) instruments...”</p>
Key question 3	<p>1. We disagree with the finding that “there are no data available to assess the short- or long-term efficacy of FAI surgery compared with no surgery.”</p> <p>2. We find inappropriate and incorrect an interpretation of the peer-reviewed literature rendered by the draft report that nearly all favorable outcomes described are confounded by other factors that may have resulted in symptom improvement independent of the surgical procedure performed.</p> <p>The draft report summarizes findings from 27 case series stating “all report improvement in pain, patient reported and clinician reported hip outcome scores, patient satisfaction and return to normal activities following FAI surgery.” The interpretation (pages 10, 14, 89, and 101) of these favorable outcomes in hundreds of patients that “whether this improvement is a result of the surgery, or the postoperative rehabilitation, or the change in activity subsequent to the surgery or placebo is not known” is inappropriate.</p>

COMMENTS on WA State HCA Draft HTA for Treatment of FAI Syndrome

- a. In fact, a large majority of patients receiving surgical repair of FAI visually confirmed at the time of surgery have served as their own control. Many reports included among the draft report's references, large and small, of FAI surgery document that prior to surgery patients have typically received conservative management for some length of time, most often three to six months or longer, during which no remission of symptoms occurred. Therefore, these patients have served as their own controls because they have failed one form of management, conservative treatment, and rapidly responded to a crossover medical intervention, surgical repair.^{1, 3, 5, 6, 8-18}
 - b. Several reports indicate that patients with symptomatic FAI as documented by clinical and radiographic evaluations do not achieve symptom resolution from extended conservative management.
 - c. A solid foundation of evidence is developing that the longer patients with symptomatic FAI, as documented by non-invasive evaluations, persist without surgical intervention, the greater is the intra-articular damage found at surgery, and the longer it takes for those patients to return to pre-injury activity levels.^{3, 19}
3. Evidence supports the application of surgical repair of symptomatic FAI despite the lack of randomized controlled trials comparing surgery with conservative care for FAI:
- a. Sufficient evidence exists documenting patient benefit from surgical repair of symptomatic FAI that it is unlikely that institutional review boards would consider such a trial ethical. This evidence has resulted in various independent provider assessments concluding coverage is appropriate.
 - b. In the United States, 239 million patient lives qualify for coverage of medically necessary and reasonable FAI surgery under private medical insurance.
 - c. Three level 1 CPT Codes for FAI were introduced in 2011. These are CPT Code 29914 (Arthroscopy, hip, surgical; with femoroplasty (ie, treatment of cam lesion); CPT Code 29915 (Arthroscopy, hip, surgical; with acetabuloplasty (ie, treatment of pincer lesion); and, CPT Code 29916 (Arthroscopy, hip, surgical; with labral repair).
 - d. Collectively, these facts offer evidence that surgical repair of symptomatic FAI unresponsive to conservative non-operative management is an accepted standard of care in the United States.
4. It is an inappropriate interpretation to use reference 29 in defense of a conclusion that there is no difference in outcomes between conservative management of "mild FAI", as described in a 37 patient Egyptian cohort, and surgical management of FAI in Western cohorts of hundreds of patients which apply a much more rigorous definition of true FAI and documentation that it in fact exists.
5. The draft report fails to understand the pathological interdependency of labral disease with bone impingement disease of the hip joint.

We disagree with the finding that there is no evidence that better outcomes result from surgery versus no surgery or from osteoplasty versus no osteoplasty. However, the latter is another indication that the draft report improperly interpreted the literature. It was reported as related to studies

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	<p>evaluating treatment of labral pathology with or without concurrent osteoplasty and therefore failed to recognize that treatment of the labral pathology in isolation is not treatment of impingement. Labral pathology is recognized to be an identifiable concurrent pathology in what was formerly diagnosed as labral disease of unknown etiology.</p> <p>6. The draft report fails to understand the distinction between surgery for labral defects and surgery for the bony defects causing FAI.</p> <p>We are confounded by the inclusion of an interpretation finding that labral debridement or refixation are considered primary surgical repair of FAI. The correct discussion would be that surgery for labral disease should not be performed in isolation if FAI is concurrently present.²⁰⁻²⁴</p>
Key Question 4	<p>1. It is inappropriate to combine outcome analysis of all surgical approaches into a single combined analysis. The analysis fails to answer the Key Question</p> <ol style="list-style-type: none"> a. All the outcome trials identified by the draft report as prospective or appear prospective were reports of arthroscopic surgery. The prospective reports missed by the draft report were arthroscopically performed. b. The nature and degree of risk with the various procedures is different and should not be combined or analyzed as if no variables exist among procedures which would affect outcomes. <p>2. It is inappropriate to combine reoperation rates from all surgical approaches into one single category intended to represent an “average” for all.</p> <ol style="list-style-type: none"> a. The draft report disparately reports that respectively, 3.8 percent and 4.4 percent of patients treated arthroscopically or by open procedure required reoperation. In other places the draft report combines results and rounds them to four percent erroneously concluding the risk of reoperation is the same for either procedure. A true interpretation would show, from the procedural detail that a 4.4 percent rate from open procedures versus a 3.8 percent rate from arthroscopic procedures on a relative basis is a nearly 16 percent higher risk. Understanding this, surgeons recognize that open surgery for FAI is appropriate for some patients when intra-articular access to the pathology is sub-optimal for arthroscopic instrumentation.
Key Question 5	<p>1. The assertion that no studies were found comparing surgery to non-surgical care must be interpreted with caution. A more appropriate finding is that studies concurrently comparing such patient cohorts are not available. Furthermore, there is good reason they are not likely be available in the future.</p> <p>Because chronic conservative management of symptomatic non-invasively documented FAI is not the present standard of care, it is inappropriate to expect that such a prospective comparison could occur. This draft report fails to recognize that many of the case series confirm that prior to surgical repair patients frequently were reported to have undergone sometimes very long periods of conservative management which did not reduce the their pain, improve their range of motion or their ability to function at their pre-injury performance level.^{1, 3, 5, 6, 8-18}</p>

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	<p>A more reasonable interpretation of the available literature is that when such patients finally receive surgical intervention, they are essentially participating in a one-way crossover trial. Many reports, large and small, of FAI surgery document that prior to surgery patients have typically received conservative management for some length of time, typically at least three to six months or more, during which period no remission of symptoms occurred.^{1,3,5,6,8-18} These patients are their own control, enabling their outcomes to be directly compared to their prior treatment. It is inappropriate to dismiss their favorable clinical response to confounding because they were not randomly allocated to conservative management, a treatment already proven ineffective.</p>
Key Question 6	<ol style="list-style-type: none">1. It is true that no cost-effectiveness, cost utility or costing studies of FAI surgery are published.2. A reasonable analysis of the literature is that despite the lack of controlled investigations of the economics of FAI surgery, it is reasonably known that more complications and longer hospitalization drive medical expenditures. It is defensible that longer rehabilitation periods result in increased time for patients before they can return to sport, full pre-injury activity or work, each and any of which increases costs to patients, employers, insurers and society. Minimally invasive surgery techniques have been developed in efforts to address each of these drivers of medical expense. Other minimally-invasive procedures have been documented to lower overall medical expense when measuring inpatient hospital expenses and overall payer expenses.²⁵⁻²⁷

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Appendix A Reference List

1. Flecher X, Dumas J, Argenson JN. Is a hip distractor useful in the arthroscopic treatment of femoroacetabular impingement? *Orthop Traumatol Surg Res* 2011;97(4):381-388.
2. Horisberger M, Brunner A, Herzog RF. Arthroscopic treatment of femoroacetabular impingement of the hip: a new technique to access the joint. *Clin Orthop Relat Res* 2010;468(1):182-190.
3. Philippon MJ, Weiss DR, Kuppersmith DA, Briggs KK, Hay CJ. Arthroscopic labral repair and treatment of femoroacetabular impingement in professional hockey players. *Am J Sports Med* 2010;38(1):99-104.
4. Stahelin L, Stahelin T, Jolles BM, Herzog RF. Arthroscopic offset restoration in femoroacetabular cam impingement: accuracy and early clinical outcome. *Arthroscopy* 2008;24(1):51-57.
5. Gedouin JE, May O, Bonin N et al. Assessment of arthroscopic management of femoroacetabular impingement. A prospective multicenter study. *Orthop Traumatol Surg Res* 2010;96(8 Suppl):S59-S67.
6. Jager M, Wild A, Westhoff B, Krauspe R. Femoroacetabular impingement caused by a femoral osseous head-neck bump deformity: clinical, radiological, and experimental results. *J Orthop Sci* 2004;9(3):256-263.
7. Pierannunzii L, d'Imporzano M. Treatment of femoroacetabular impingement: a modified resection osteoplasty technique through an anterior approach. *Orthopedics* 2007;30(2):96-102.
8. Emará K, Samir W, Motasem EL, Ghafar KA. Conservative treatment for mild femoroacetabular impingement. *J Orthop Surg (Hong Kong)* 2011;19(1):41-45.
9. Bizzini M, Notzli HP, Maffiuletti NA. Femoroacetabular impingement in professional ice hockey players: a case series of 5 athletes after open surgical decompression of the hip. *Am J Sports Med* 2007;35(11):1955-1959.
10. Byrd JW, Jones KS. Arthroscopic femoroplasty in the management of cam-type femoroacetabular impingement. *Clin Orthop Relat Res* 2009;467(3):739-746.
11. Byrd JW, Jones KS. Arthroscopic management of femoroacetabular impingement in athletes. *Am J Sports Med* 2011;39 Suppl:7S-13S.
12. Graves ML, Mast JW. Femoroacetabular impingement: do outcomes reliably improve with surgical dislocations? *Clin Orthop Relat Res* 2009;467(3):717-723.
13. Haviv B, O'Donnell J. Arthroscopic treatment for symptomatic bilateral cam-type femoroacetabular impingement. *Orthopedics* 2010;33(12):874.
14. Javed A, O'Donnell JM. Arthroscopic femoral osteochondroplasty for cam femoroacetabular impingement in patients over 60 years of age. *J Bone Joint Surg Br* 2011;93(3):326-331.

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15. Philippon M, Schenker M, Briggs K, Koppersmith D. Femoroacetabular impingement in 45 professional athletes: associated pathologies and return to sport following arthroscopic decompression. *Knee Surg Sports Traumatol Arthrosc* 2007;15(7):908-914.
16. Philippon MJ, Yen YM, Briggs KK, Koppersmith DA, Maxwell RB. Early outcomes after hip arthroscopy for femoroacetabular impingement in the athletic adolescent patient: a preliminary report. *J Pediatr Orthop* 2008;28(7):705-710.
17. Singh PJ, O'Donnell JM. The outcome of hip arthroscopy in Australian football league players: a review of 27 hips. *Arthroscopy* 2010;26(6):743-749.
18. Yun HH, Shon WY, Yun JY. Treatment of femoroacetabular impingement with surgical dislocation. *Clin Orthop Surg* 2009;1(3):146-154.
19. Leunig M, Beaulé PE, Ganz R. The concept of femoroacetabular impingement: current status and future perspectives. *Clin Orthop Relat Res* 2009;467(3):616-622.
20. Burnett RS, Della Rocca GJ, Prather H, Curry M, Maloney WJ, Clohisy JC. Clinical presentation of patients with tears of the acetabular labrum. *J Bone Joint Surg Am* 2006;88(7):1448-1457.
21. Heyworth BE, Shindle MK, Voos JE, Rudzki JR, Kelly BT. Radiologic and intraoperative findings in revision hip arthroscopy. *Arthroscopy* 2007;23(12):1295-1302.
22. May O, Matar WY, Beaulé PE. Treatment of failed arthroscopic acetabular labral debridement by femoral chondro-osteoplasty: a case series of five patients. *J Bone Joint Surg Br* 2007;89(5):595-598.
23. Nepple JJ, Zebala LP, Clohisy JC. Labral Disease Associated With Femoroacetabular Impingement: Do We Need to Correct the Structural Deformity? *J Arthroplasty* 2009;24(6):114-119.
24. Philippon MJ, Schenker ML, Briggs KK, Koppersmith DA, Maxwell RB, Stubbs AJ. Revision hip arthroscopy. *Am J Sports Med* 2007;35(11):1918-1921.
25. Pruzansky ME, Remer S, Freedman B. The effect of arthroscopic surgery of the knee on hospital utilization. *Health Serv Res* 1989;24(5):685-692.
26. Peterson KS, Lee MS, Buddecke DE. Arthroscopic versus open ankle arthrodesis: a retrospective cost analysis. *J Foot Ankle Surg* 2010;49(3):242-247.
27. Barber FA, Click SD, Weideman CA. Arthroscopic or open Bankart procedures: what are the costs? *Arthroscopy* 1998;14(7):671-674.

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APPENDIX B.

Comments By Page of Draft Report

Page	Concern	Detail
6-7	Issue	Key questions 3, 4, 5, and 6 as specified in the draft report are different from the published Final Key Questions. It is not appropriate to evaluate surgical repair for symptomatic FAI against a standard of no surgery. Regardless, the draft report fails to recognize that patients in most trials served as their own controls. One criteria for surgery frequently identified, was six months or longer of conservative management that had failed to resolve the symptoms resulting in the patients not being able to perform activities at the level that existed prior to symptom onset. Because of this, patients actually served as their own controls in one-way crossover trials.
9,12, 47,100	Issue	<ol style="list-style-type: none"> <li data-bbox="464 709 1410 1192">1. The appraisal states “inclusion and exclusion criteria of a clinical trial define the population of interest, in this case, those thought to have FAI.” The report appears to fail to recognize that the case definition applied in a majority of peer-reviewed publications, generally retrospective analysis of prospectively collected data, originated from visual documentation at surgery that the patients had bony impingement. Rather, it focused on the ability of what it calls the “case definition” to accurately reflect within individual reports the predictive reliability of well accepted non-invasive diagnostic criteria for FAI to reliably identify patients confirmed during surgery to have actual hip impingement. As a result, the draft report appears to be challenging the validity of the majority of publications evaluating patient outcomes following intra-operatively confirmed bony impingement in hip joints. The result is a report that inappropriately understates the favorable outcomes revealed in the peer-reviewed literature. It fails to differentiate outcomes according to the surgical technique applied in the repair and the report itself demonstrates inconsistency in study evaluation. <li data-bbox="464 1224 1410 1413">2. The definition of FAI is well established across the spectrum of primary, secondary and tertiary literature. FAI has been described and is defined by intra-operative pathoanatomic visual findings. Non-invasive clinical and radiographic evidence of the anatomic pathology have been subsequently associated based on numerous peer-reviewed publications of various classifications since the pathoanatomy was first conceptualized as a unique entity and defined in 1999.¹ <li data-bbox="464 1444 1410 1602">3. In 2011, The National Library of Medicine introduced the Medical Subject Heading, “Femoracetabular Impingement” defining it as “A pathologic mechanical process that can lead to hip failure. It is caused by abnormalities of the ACETABULUM and/or femur combined with rigorous hip motion, leading to repetitive collisions that damage the soft tissue structures.”² <li data-bbox="464 1633 1410 1822">4. Stoller’s Atlas of Orthopaedics and Sports Medicine identifies that FAI is “caused by an abnormal abutment between the proximal femur and the acetabular rim” and that it presents in cam, pincer and mixed cam-pincer morphologies of which the latter is most frequently reported. Further details are provided including 21 figures (Stoller’s figures 3.101 to 3.121) displaying in fine detail the pathologic abnormalities.^{2,3}

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Page	Concern	Detail
10,14, 89,101	Error	<ol style="list-style-type: none"> 1. The statement that “there is no evidence that one specific treatment resulted in better outcomes than another” is not based in fact. Numerous studies referenced in the draft report but questionably discredited reasonably provide consistent evidence that patients receive benefit from surgical repair of FAI. The statement in the draft report that “27 case series were found that reported on clinical outcomes following treatment for FAI in non- or recreational athletes. All report improvement in pain, patient reported and clinical reported hip outcome scores, patient satisfaction and return to normal activities following FAI surgery,” should stand without the inappropriate qualification following it. 2. A 2010 systematic review of six common indications routinely applied for hip arthroscopy concluded that the level of evidence among all was highest for FAI at grade B. All other indications received a lower grading for the level of supporting evidence.⁴ This source is included in the draft report references.
10	Error	The draft report incorrectly identifies two studies comparing concurrent osteoplasty or no osteoplasty as “...studies which investigated the effectiveness of various surgical treatments for FAI.” Rather, these studies evaluated the failure rate of isolated labral surgery when FAI repair was not performed in the presence of bony impingement. ^{5,6}
10	Error	The draft report incorrectly identifies two studies comparing labral debridement to labral refixation as “...studies which investigated the effectiveness of various surgical treatments for FAI.”
10, many	Issue	<p>An Egyptian study⁷ published in a Hong Kong journal of 37 patients with “Mild FAI” but excluded from participation in the study if they had evidence of “major bony pathology” should not have received the credibility and focus provided to it throughout the report.</p> <p>Emara, et.al. report in an Egyptian population that 33 of 37 patients with “mild” FAI responded favorably to conservative management when measured at 25 – 28 months so long as they modified their lifestyle to avoid impingement activities.⁷ It is not unreasonable to question whether the reported patients had FAI as defined in the majority of Western literature. The report did not define how degrees of FAI severity were assessed. It did state that patients were excluded if their alpha angle exceeded 60 degrees or radiographic assessment revealed “any evidence of hip arthritis or a non-spherical femoral head,” or “major bony pathology.” No definition of what was meant by “bony pathology” was provided nor was the scale identifying what was considered “major” pathology from lesser pathology. Finally, the report states that patients were instructed to perform physiotherapy that included “stretching exercises.” It is typically believed, as stated by Parvizi, et.al. (draft report reference 97) that, “Physical therapy with an emphasis on improving passive range of motion or stretching is largely counterproductive and exacerbates the symptoms.”⁸</p>

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Page	Concern	Detail
10	Issue	<p>Please reconcile the below sections of the draft report, page 10 with page 60: "...but only two <u>were evaluated</u> for validity and/or reliability in an FAI population: " and "<u>Neither of these measures was adequately tested</u> for validity or reliability in the FAI population."</p> <p>Issue is noted on page 60 and 74: "Of these, <u>two outcome measures have been validated</u> in FAI patients: HOS-D and M-WOMAC (12)." contrasted with the summary conclusions on page 74 that "only one (NAHS) of the three instruments was adequately tested for validity, and it was performed in a young hip-pain patient population. Content <u>validity was inadequate</u> for the other two (HOS, M-WOMAC) instruments..."</p>
12	Error	The Tonnis Classification of hip dysplasia is not an outcome criterion for response to FAI surgery.
14	Error	The draft report inappropriately presents a simple average of reoperation rates reported for arthroscopic and open surgery for symptomatic FAI. This fails to distinguish the relative nearly 16 percent lower rate of reoperation noted elsewhere in the draft report of 3.8 percent for arthroscopy and 4.4 percent for open procedures.
16	Error	<p>The draft report fails to elucidate evidence that "the causes of hip pain, the natural history of FAI, and its relationship to osteoarthritis are unclear..." Rather, labral pathology as a source of the pain and various levels of evaluation deliver evidence on these relationships.⁹⁻¹³ On page 21, the draft report identifies that its reference 40 identified that a pistol grip deformity was associated with hip osteoarthritis.</p> <p>Ganz, et.al. elucidate the data supporting the association between unrepaired FAI and the progression or development of osteoarthritis and identify that "the strategy of treatment [for FAI] should be to reconstruct a hip morphology allowing motion not interrupted by FAI before major rim and cartilage damage is established."¹¹ Parvizi and colleagues⁸ and Leunig and associates¹⁴ concur that not treating FAI in symptomatic patients risks progression of the pathology to osteoarthritis. The former state, "continued FAI leads to progression of the destructive process and advancement of labral and chondral lesions"⁸ while the latter state that "delay in the surgical correction of symptomatic patients with these bony abnormalities may lead to disease progression to the point where joint preservation is no longer indicated."¹⁴ Parvizi and colleagues go on to say that in younger patients conservative management may be "temporarily successful" but that "...such treatment usually fails to control the symptoms. Vaughn and Safran, despite recognizing that at the present time no evidence proves that surgery for FAI prevents the development of osteoarthritis, conclude that in asymptomatic patients with FAI morphology, "once the patient becomes symptomatic, then early surgical intervention is recommended before the damage to the joint becomes too advanced."¹⁵</p>
16	Error	The draft report generalizes hip surgery as an "invasive procedure." On page 29 it states, "Hip arthroscopy is a minimally invasive procedure..." Considering that the

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Page	Concern	Detail
		report was tasked with identifying differences between surgical procedures used to repair FAI, this seeming difference is not identified.
16	Issue	Characterizing joint pathology as “relatively minor abnormalities” is an inappropriate opinion not based on evidence presented in the draft report.
29	Error	Reference 119 of the draft report is incorrectly identified as a meta-analysis. It is a systematic review and was excluded from the discussion evaluating the merits of evidence supporting surgical treatment, and in this case specifically arthroscopic treatment, of FAI. ⁴
31	Error	The draft report fails to reflect the fact that the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom updated its guidance in July 2011 on FAI surgery directionally changing the recommendation. The principal finding is that “Current evidence on the efficacy of open femoro-acetabular surgery for hip impingement syndrome is adequate in terms of symptom relief in the short and medium term.” A separate guidance on the arthroscopic repair is expected to follow shortly.
31	Issue	<ol style="list-style-type: none"> 1. In discussing the systematic review by Bedi, et al¹⁶ the draft report mentions one of three conclusions of the paper that supports a conclusion the draft report had made. 2. The draft report fails to identify the three purposes defined for the analyses performed in the Bedi, et al paper, literature quality, differences in patient satisfaction between open and arthroscopic repair and differences in outcome between open and arthroscopic repair. The authors’ conclusion regarding the other two questions addressed was, “our hypothesis that arthroscopic techniques are as effective as open surgical techniques in achieving satisfactory clinical outcomes in the treatment of FAI and labral pathology was supported.”¹⁶
32	Issue	<ol style="list-style-type: none"> 1. The draft review discusses detail and some findings of a systematic review of treatment for FAI performed by Clohisy and colleagues.¹⁷ The review highlights statements made by the authors supporting a conclusion of the draft report. 2. The draft review fails to present in balance the authors’ concluding statement, “In conclusion, our review of the literature suggests hip impingement surgery is associated with early relief of pain and improved function.”¹⁷ This conclusion is in contradiction to the conclusion presented in the draft report.
32-33		<ol style="list-style-type: none"> 1. The draft review fails to identify and discuss three additional peer-reviewed systematic reviews of FAI surgery.¹⁸⁻²⁰ <ol style="list-style-type: none"> a. Botser, et al review open, combined and arthroscopic surgery for FAI and conclude, “Surgical treatment of FAI has shown consistent positive outcomes with all 3 approaches reviewed in this article” and, “However, the arthroscopic method showed the greatest short-term improvement in mHHS and the lowest rate of complications.”¹⁸ b. Matsuda and colleagues review open dislocation, mini-open, and arthroscopic surgeries for femoroacetabular impingement, concluding, “The open dislocation, mini-open, and arthroscopic methods for treating

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Page	Concern	Detail
		<p style="text-align: center;">symptomatic FAI are effective in improving pain and function in short-term to midterm studies and are relatively safe procedures.”¹⁹</p> <p>2. Ng et al evaluate surgical treatment of FAI regardless of procedure and conclude, “Surgical treatment for FAI reliably improves patient symptoms in the majority of patients without advanced osteoarthritis or chondral damage.”²⁰</p>
47	Error	<ol style="list-style-type: none"> 1. The draft report states (4.1.3) that eight reports were identified that “appeared to be prospective.” However, it goes on to say that five of these do not “describe inclusion criteria for the study.” Contrary to this determination, on close inspection, three of these five indicate that pre-operative clinical and radiographic assessments were consistent with accepted criteria associated with FAI and impingement was found at surgery in all patients.²¹⁻²³ One²¹ of these specifically comments on the occasional mis-alignment of pre-operative radiographic assessment and intra-operative finding. However, on page 75 of the draft report, another²² of these three “prospective” reports is discussed in detail and called a “retrospective cohort” study. This failure to consistently apply the draft report’s own criteria throughout the report confounds the report’s reliability. 2. Among the two studies lacking clear criteria for patient inclusion, one is an Egyptian study of 37 patients that excluded those with “major bony pathology” and was designed to evaluate conservative management attained by permanent lifestyle modification.⁷ It is not unreasonable to question the relative comparability of this population to the majority of surgical intervention studies in the Western literature. 3. For none of the three identified prospective reports does there appear to be a statement identifying the fact that all patients receiving surgery had impingement confirmed. This despite one stated purpose of this section of the report (draft report pages 9 and 46) to be to contrast the intra-operative visual inspection results as a “reference standard” to the non-invasive pre-operative clinical and radiographic assessments as a means of evaluating the diagnostic validity of those pre-operative determinations. 4. Furthermore, by focusing on the pre-operative diagnosis rather than the purpose of the published report evaluated, it was not recognized that one of the three prospective studies was a technical evaluation of an adjunctive device rather than a clinical evaluation of surgery outcome.²⁴ It is inappropriate to include this report in an evaluation of the clinical outcomes of FAI surgery. 5. Finally, five additional prospective²⁵⁻²⁹ studies were not included in this analysis, although one of these²⁷, despite stating within its description of methods that it included a consecutive series of patients “prospectively studied” has been labeled as retrospective elsewhere.¹⁹

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Page	Concern	Detail
47	Error	The draft report claims Gedouin does not describe included patients. Actually the article states, "Surgery was indicated for disabling symptomatology of more than six months' duration. Included patients presented with clinical and radiological signs of impingement (1)." This adequately describes by scientific standards the patient inclusion. The second sentence refers to a tertiary reference source for a description of the events qualifying the diagnosis. This is acceptable practice. Furthermore, the description does not seem materially different from that accepted in draft report reference 101.
47	Error	Table 5 fails to correctly characterize patient inclusion criteria used for Philippon, et.al. (draft report reference 101). The paper identifies that patients had "a minimum 6 weeks" of non-operative treatment prior to surgery, "the average time from onset of symptoms to date of surgery was 19 months," and that patients had a positive anterior impingement sign and/or a positive FABER test. A positive FABER test indicates a limited range of motion in the affected hip.
47	Error	The draft report claims Jager does not describe included patients. Actually the article states, "Typical radiographic findings of osseous bump deformities on the anterolateral head-neck junction were found in 22 hips of 17 patients (13 men, 4 women). All of the patients showed typical symptoms of femoroacetabular impingement." This is a reasonable statement qualifying the investigated patients. However, some patients included in this trial would not have been or would not be included in most controlled published prospective or retrospective series of FAI patients due to etiology or secondary findings. Two of these patients were diagnosed as having "severe osteoarthritis" which is an exclusion criterion for most FAI investigations performed today. This is reflective of the fact that this is an evolving science with current practice being modified by evidence previously reported.
47	Error	Flecher, et.al. was identified as one of three studies considered prospective (draft report reference 31). This was a technical study of a hip distractor adjunctively used for arthroscopic surgery for FAI. It did not evaluate the outcome of the surgery itself.
47	Issue	The draft report places the reference Emara, et.al. 2010 (draft report reference 29) as one that appeared to be prospective. The report does not identify whether the data was collected prospectively or retrospectively. More significantly, it is not unreasonable to question whether the reported patients had FAI as defined in the majority of Western literature. The report specifies that patients had "mild" FAI without defining how degrees of severity were assessed. It also states that included patients could not have "major bony pathology" without defining what was meant by "bony pathology" or differentiating a severity of "major" pathology from something else. Finally, the report states that patients were instructed to perform physiotherapy that included "stretching exercises." It is typically believed, as stated by Parvizi, et.al. (draft report reference 97) that, "Physical therapy with an emphasis on improving passive range of motion or stretching is largely counterproductive and exacerbates the symptoms."
47	Issue	The draft report places the reference Philippon, et.al. 2010 (draft report reference 101) as one that appeared to be prospective. The report states that although data was prospectively collected it was retrospectively analyzed. The authors self-classify the

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Page	Concern	Detail
		report as presenting Grade IV evidence.
47	Issue	The annotated review of Bardakos et.al. 2008 (2) stated the osteoplasty (OP) group had "slightly worse" function at baseline compared to non-OP group. Original report found no difference between groups in the overall Modified HHS score. (P=0.59)
49	Issue	The draft report fails to evaluate a dissenting opinion of the principal work they describe purporting to document poor performance of the α -angle in evaluating the presence of FAI. ³⁰
54	Error	The statement relative to no consistent case definition for FAI in prospective studies is addressed in the detail for page 47 of this document.
59	Error	The Tonnis Classification system is used to grade the severity of hip osteoarthritis evaluated on radiographs.
60,74	Error	<p>We have difficulty reconciling the statement on page 60, "Of these, two outcome measures have been validated in FAI patients: HOS-D and M-WOMAC (12)." with the summary conclusions on page 74 that "only one (NAHS) of the three instruments was adequately tested for validity, and it was performed in a young hip-pain patient population. Content validity was inadequate for the other two (HOS, M-WOMAC) instruments..."</p> <p>The first statement (page 60) is also inconsistent with a similar statement found on page 10 of the draft report.</p>
75	Error	The draft report incorrectly reports isolated labral surgery as surgery to repair FAI.
75	Error	The draft report incorrectly assesses two studies whose purpose was to evaluate corrective labral surgery alone versus combined with concurrent osteoplasty for impingement as assessing the outcome of FAI surgery. ^{5,6}
75	Issue	Section 4.3.2 and Table 9 are flawed in evaluation of the literature demonstrating a lack of understanding by the draft report team. The citations described here relate to labral surgery which in isolation is a different surgery than FAI surgery. However, that said, because labral disease is interdependent with the presence of FAI, the conditions are not unrelated. ^{6,31-37}
79	Issue	In evaluating the Bardakos et al 2008 study the draft report states, "The no osteoplasty group had slightly worse function pre-operatively compared with the osteoplasty group..." as based on the modified Harris Hip Score. This is a biased statement lacking objectivity because the work states that there was no significant difference in this parameter between groups (P=0.59). ⁵
80	Error	An important error in the discussion of the Bardakos et al 2008 study was reporting that there was no significant difference (P=0.06) in the excellent/good scores for the osteoplasty group compared to the no osteoplasty group. In fact, the paper reported a significant difference favoring the osteoplasty group (P=0.043). ⁵
80	Error	The annotated review of Bardakos et.al. 2008 (draft report reference 2) states that clinical follow-up was by "follow-up visit" or telephone interview. The latter is correct but the former was follow-up by mail. ⁵

COMMENTS on WA State HCA Draft HTA for Treatment of FAI Syndrome

Page	Concern	Detail
83	Issue	The draft report fails to expand on the volume of peer-reviewed reports and the number of patients and hips according to type of surgery.
89	Error	Errors in interpretation of the presented summary information for short-term effectiveness of FAI surgery have already been described earlier in this table.
90	Issue	The quantity and severity of complications related to the different surgical approaches to FAI repair are not well discussed in the draft report. The tables alone are insufficient to represent a considered interpretation of the published facts and quantity of literature differentiating the issues.
91	Error	We question the appropriateness of including a single report of a severe complication of arthroscopy in a patient with a hip pathology unrelated to the remit. This complication occurred in a patient treated for a acetabular fracture and not FAI.
91	Issue	What is "symptomatic hardware?"
94	Error	The draft report summary mis-represents the data by inappropriately combining the simple average of reoperation rates for patients following arthroscopic or open repair of FAI. The risk of reoperation for open repair is relatively about 16 percent higher than that for arthroscopic repair.
96	Error	<p>The summary represents multiple interpretive errors in that the draft report fails to recognize that numerous retrospective analyses of prospectively collected data identify that patients often served as their own controls because surgery was performed only in those patients who failed to respond to an appropriate duration of conservative management.^{7, 21, 22, 24, 26, 29, 38-46} These reports are included in the draft report reference but were inappropriately dismissed as poor evidence during the review process.</p> <p>FAI is a relatively new entity and the approach to treatment is an evolving science. However, early in its evaluation, Jager and colleagues well documented the failure of conservative treatment to successfully resolve the expressed symptoms when the underlying pathology was not surgically repaired.²² With such documentation, it becomes difficult for institutional review boards or practicing surgeons to ethically approve of comparative clinical evaluations in which one treatment group would receive no treatment because evidence existed that no treatment is ineffective. From a practical perspective, it is difficult to imagine a patient agreeing to such a randomization during an informed consent process.</p> <p>The expectation of the Washington State HCA that such evidence should exist is unreasonable. The ethics of changing the final Key Questions to require such a comparison would make for an interesting discussion.</p>

COMMENTS on WA State HCA Draft HTA for Treatment of FAI Syndrome

Page	Concern	Detail
100-102	Issue	<p>In the summary for Key Question 3 on page 101, the effectiveness section specifically comments on one study purporting to present evidence on the clinical outcomes of patients with FAI who were managed conservatively. This is another example of the mis-weighting and biased credit given to the Emara et al study⁷ because the detail of this study was not critically appraised or discussed in the body of the draft report. A fair appraisal of comparable rigor as applied to reports of favorable clinical outcomes of surgical repair of FAI should have discovered issues of concern with the case definition applied in this report.</p> <p>Other comments on the findings reported in the final summary have been defined throughout this table.</p>

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Appendix B Reference List

1. Myers SR, Eijer H, Ganz R. Anterior femoroacetabular impingement after periacetabular osteotomy. *Clin Orthop Relat Res* 1999;(363):93-99.
2. MeSH. Femoroacetabular Impingement. National Library of Medicine, National Institute of Health, 2011 (Accessed August 9, 2011 http://www.nlm.nih.gov/cgi/mesh/2011/MB_cgi?mode=&index=25682).
3. Stoller DW. The Hip: Pearls and Pitfalls & Color Illustrations. In: Stoller DW, editor. *Stoller's Atlas of Orthopaedics and Sports Medicine*. New York: Lippincott Williams & Wilkins; 2008:125-259.
4. Stevens MS, Legay DA, Glazebrook MA, Amirault D. The evidence for hip arthroscopy: grading the current indications. *Arthroscopy* 2010;26(10):1370-1383.
5. Bardakos NV, Vasconcelos JC, Villar RN. Early outcome of hip arthroscopy for femoroacetabular impingement: the role of femoral osteoplasty in symptomatic improvement. *J Bone Joint Surg Br* 2008;90(12):1570-1575.
6. Nepple JJ, Zebala LP, Clohisy JC. Labral Disease Associated With Femoroacetabular Impingement: Do We Need to Correct the Structural Deformity? *J Arthroplasty* 2009;24(6):114-119.
7. Emara K, Samir W, Motasem EL, Ghafar KA. Conservative treatment for mild femoroacetabular impingement. *J Orthop Surg (Hong Kong)* 2011;19(1):41-45.
8. Parvizi J, Leunig M, Ganz R. Femoroacetabular impingement. *J Am Acad Orthop Surg* 2007;15(9):561-570.
9. Audenaert EA, Mahieu P, Pattyn C. Three-dimensional assessment of cam engagement in femoroacetabular impingement. *Arthroscopy* 2011;27(2):167-171.
10. Beck M, Kalhor M, Leunig M, Ganz R. Hip morphology influences the pattern of damage to the acetabular cartilage: femoroacetabular impingement as a cause of early osteoarthritis of the hip. *J Bone Joint Surg Br* 2005;87(7):1012-1018.
11. Ganz R, Leunig M, Leunig-Ganz K, Harris WH. The etiology of osteoarthritis of the hip: an integrated mechanical concept. *Clin Orthop Relat Res* 2008;466(2):264-272.
12. Martin DE, Tashman S. The Biomechanics of Femoroacetabular Impingement. *Operative Techniques in Orthopaedics* 2010;20(4):248-254.
13. Tanzer M, Noiseux N. Osseous abnormalities and early osteoarthritis: the role of hip impingement. *Clin Orthop Relat Res* 2004;(429):170-177.
14. Leunig M, Beaulé PE, Ganz R. The concept of femoroacetabular impingement: current status and future perspectives. *Clin Orthop Relat Res* 2009;467(3):616-622.

COMMENTS on WA State HCA Draft HTA for Treatment of FAI Syndrome

15. Vaughn ZD, Safran MR. Arthroscopic femoral osteoplasty/chielectomy for cam-type femoroacetabular impingement in the athlete. *Sports Med Arthrosc* 2010;18(2):90-99.
16. Bedi A, Chen N, Robertson W, Kelly BT. The management of labral tears and femoroacetabular impingement of the hip in the young, active patient. *Arthroscopy* 2008;24(10):1135-1145.
17. Clohisy JC, St John LC, Schutz AL. Surgical treatment of femoroacetabular impingement: a systematic review of the literature. *Clin Orthop Relat Res* 2010;468(2):555-564.
18. Botser IB, Smith TW, Jr., Nasser R, Domb BG. Open surgical dislocation versus arthroscopy for femoroacetabular impingement: a comparison of clinical outcomes. *Arthroscopy* 2011;27(2):270-278.
19. Matsuda DK, Carlisle JC, Arthurs SC, Wierks CH, Philippon MJ. Comparative systematic review of the open dislocation, mini-open, and arthroscopic surgeries for femoroacetabular impingement. *Arthroscopy* 2011;27(2):252-269.
20. Ng VY, Arora N, Best TM, Pan X, Ellis TJ. Efficacy of surgery for femoroacetabular impingement: a systematic review. *Am J Sports Med* 2010;38(11):2337-2345.
21. Gedouin JE, May O, Bonin N et al. Assessment of arthroscopic management of femoroacetabular impingement. A prospective multicenter study. *Orthop Traumatol Surg Res* 2010;96(8 Suppl):S59-S67.
22. Jager M, Wild A, Westhoff B, Krauspe R. Femoroacetabular impingement caused by a femoral osseous head-neck bump deformity: clinical, radiological, and experimental results. *J Orthop Sci* 2004;9(3):256-263.
23. Stahelin L, Stahelin T, Jolles BM, Herzog RF. Arthroscopic offset restoration in femoroacetabular cam impingement: accuracy and early clinical outcome. *Arthroscopy* 2008;24(1):51-57.
24. Flecher X, Dumas J, Argenson JN. Is a hip distractor useful in the arthroscopic treatment of femoroacetabular impingement? *Orthop Traumatol Surg Res* 2011;97(4):381-388.
25. Brunner A, Horisberger M, Herzog RF. Sports and recreation activity of patients with femoroacetabular impingement before and after arthroscopic osteoplasty. *Am J Sports Med* 2009;37(5):917-922.
26. Byrd JW, Jones KS. Arthroscopic femoroplasty in the management of cam-type femoroacetabular impingement. *Clin Orthop Relat Res* 2009;467(3):739-746.
27. Ilizaliturri VM, Jr., Orozco-Rodriguez L, Acosta-Rodriguez E, Camacho-Galindo J. Arthroscopic treatment of cam-type femoroacetabular impingement: preliminary report at 2 years minimum follow-up. *J Arthroplasty* 2008;23(2):226-234.
28. Philippon MJ, Briggs KK, Yen YM, Koppersmith DA. Outcomes following hip arthroscopy for femoroacetabular impingement with associated chondrolabral dysfunction: minimum two-year follow-up. *J Bone Joint Surg Br* 2009;91(1):16-23.

COMMENTS on WA State HCA Draft HTA for Treatment of FAI Syndrome

29. Byrd JW, Jones KS. Arthroscopic management of femoroacetabular impingement in athletes. *Am J Sports Med* 2011;39 Suppl:7S-13S.
30. Beaulé PE, Rakhra K. Cam-type FAI: is the alpha angle the best MR arthrography has to offer? (*Skeletal Radiol* 2009;38(9):855-62). *Skeletal Radiol* 2010;39(2):201-202.
31. Burnett RS, Della Rocca GJ, Prather H, Curry M, Maloney WJ, Clohisy JC. Clinical presentation of patients with tears of the acetabular labrum. *J Bone Joint Surg Am* 2006;88(7):1448-1457.
32. Espinosa N, Rothenfluh DA, Beck M, Ganz R, Leunig M. Treatment of femoro-acetabular impingement: preliminary results of labral refixation. *J Bone Joint Surg Am* 2006;88(5):925-935.
33. Heyworth BE, Shindle MK, Voos JE, Rudzki JR, Kelly BT. Radiologic and intraoperative findings in revision hip arthroscopy. *Arthroscopy* 2007;23(12):1295-1302.
34. Larson CM, Giveans MR. Arthroscopic debridement versus refixation of the acetabular labrum associated with femoroacetabular impingement. *Arthroscopy* 2009;25(4):369-376.
35. May O, Matar WY, Beaulé PE. Treatment of failed arthroscopic acetabular labral debridement by femoral chondro-osteoplasty: a case series of five patients. *J Bone Joint Surg Br* 2007;89(5):595-598.
36. Philippon MJ, Schenker ML, Briggs KK, Kuppersmith DA, Maxwell RB, Stubbs AJ. Revision hip arthroscopy. *Am J Sports Med* 2007;35(11):1918-1921.
37. Meermans G, Konan S, Haddad FS, Witt JD. Prevalence of acetabular cartilage lesions and labral tears in femoroacetabular impingement. *Acta Orthop Belg* 2010;76(2):181-188.
38. Bizzini M, Notzli HP, Maffiuletti NA. Femoroacetabular impingement in professional ice hockey players: a case series of 5 athletes after open surgical decompression of the hip. *Am J Sports Med* 2007;35(11):1955-1959.
39. Graves ML, Mast JW. Femoroacetabular impingement: do outcomes reliably improve with surgical dislocations? *Clin Orthop Relat Res* 2009;467(3):717-723.
40. Haviv B, O'Donnell J. Arthroscopic treatment for symptomatic bilateral cam-type femoroacetabular impingement. *Orthopedics* 2010;33(12):874.
41. Javed A, O'Donnell JM. Arthroscopic femoral osteochondroplasty for cam femoroacetabular impingement in patients over 60 years of age. *J Bone Joint Surg Br* 2011;93(3):326-331.
42. Philippon M, Schenker M, Briggs K, Kuppersmith D. Femoroacetabular impingement in 45 professional athletes: associated pathologies and return to sport following arthroscopic decompression. *Knee Surg Sports Traumatol Arthrosc* 2007;15(7):908-914.
43. Philippon MJ, Yen YM, Briggs KK, Kuppersmith DA, Maxwell RB. Early outcomes after hip arthroscopy for femoroacetabular impingement in the athletic adolescent patient: a preliminary report. *J Pediatr Orthop* 2008;28(7):705-710.

COMMENTS on WA State HCA Draft HTA for Treatment of FAI Syndrome

44. Philippon MJ, Weiss DR, Koppersmith DA, Briggs KK, Hay CJ. Arthroscopic labral repair and treatment of femoroacetabular impingement in professional hockey players. *Am J Sports Med* 2010;38(1):99-104.
45. Singh PJ, O'Donnell JM. The outcome of hip arthroscopy in Australian football league players: a review of 27 hips. *Arthroscopy* 2010;26(6):743-749.
46. Yun HH, Shon WY, Yun JY. Treatment of femoroacetabular impingement with surgical dislocation. *Clin Orthop Surg* 2009;1(3):146-154.

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Appendix C.

FAI Surgery Coverage Policy by U.S. Medical Insurers

BCBSA-Blue Cross Blue Shield Association	Covered Lives	Hip Arthroscopic/Hip Open for FAI Coverage Policy	Clinical Criteria
<p>Publicly traded companies</p> <ul style="list-style-type: none"> • <u>Anthem for-profit (WellPoint)</u> <ul style="list-style-type: none"> ○ Anthem Blue Cross Blue Shield <ul style="list-style-type: none"> ▪ Colorado ▪ Connecticut ▪ Indiana ▪ Kentucky ▪ Maine ▪ Missouri ▪ Nevada ▪ New Hampshire ▪ Ohio ▪ Parts of Virginia ▪ Wisconsin ○ <u>Anthem Blue Cross</u> <ul style="list-style-type: none"> ▪ California ○ Blue Cross Blue Shield of Georgia ○ Empire Blue Cross and Blue Shield (New York) 	<p>100MM + 39 Separate health insurance organizations and companies in the U.S. Combined</p>	<p>Covered</p>	<p>http://www.anthem.com/health-insurance/home/overview</p>
<p>Multi-state private companies</p> <ul style="list-style-type: none"> • CareFirst <ul style="list-style-type: none"> ○ District of Columbia ○ Maryland ○ Parts of Virginia 	<p>Above</p>	<p>Covered</p>	<p>https://provider.carefirst.com</p>

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<ul style="list-style-type: none"> • <u>Health Care Service Corporation</u> <ul style="list-style-type: none"> ○ Blue Cross Blue Shield of Illinois ○ Blue Cross Blue Shield of New Mexico ○ Blue Cross Blue Shield of Oklahoma ○ Blue Cross Blue Shield of Texas • <u>Highmark</u> <ul style="list-style-type: none"> ○ Highmark Blue Cross Blue Shield (Western Pennsylvania) ○ Highmark Blue Shield (Eastern & Central Pennsylvania) ○ Mountain State Blue Cross and Blue Shield (West Virginia) • <u>Premera</u> <ul style="list-style-type: none"> ○ Premera Blue Cross Blue Shield of Alaska ○ Premera Blue Cross (Washington) • <u>The Regence Group</u> <ul style="list-style-type: none"> ○ Regence Blue Shield of Idaho ○ Regence Blue Cross Blue Shield of Oregon ○ Regence Blue Cross Blue Shield of Utah ○ Regence Blue Shield (Washington) • <u>Well mark Blue Cross Blue Shield</u> <ul style="list-style-type: none"> ○ Iowa ○ South Dakota 		<p>http://www.hcsc.com/index.html</p> <p>https://prc.highmark.com/rseprc/hbcbs/pub</p> <p>https://www.premera.com</p> <p>http://www.regence.com/index.jsp</p> <p>www.wellmark.com</p>
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<p>Single-state or regional companies</p> <ul style="list-style-type: none"> • <u>Blue Cross and Blue Shield of Alabama</u> • Blue Cross Blue Shield of Arizona • Arkansas Blue Cross Blue Shield • <u>Blue Shield of California</u> • Blue Cross Blue Shield of Delaware • Blue Cross Blue Shield of Florida • <u>Hawaii Medical Service Association</u> • Blue Cross of Idaho • Blue Cross Blue Shield of Kansas • Blue Cross Blue Shield of Louisiana • Blue Cross Blue Shield of Massachusetts • <u>Blue Cross Blue Shield of Michigan</u> • Blue Cross Blue Shield of Minnesota • Blue Cross Blue Shield of Mississippi • Blue Cross Blue Shield of Kansas City (Missouri) • Blue Cross Blue Shield of Montana • Blue Cross Blue Shield of Nebraska • <u>Horizon Blue Cross Blue Shield of New Jersey</u> • <u>Excellus Blue Cross Blue Shield (Central New York)</u> • Blue Shield of Northeastern New York • Blue Cross Blue Shield of Western New York • Blue Cross Nevada • Blue Cross Blue Shield of North Carolina • Blue Cross Blue Shield of North Dakota • Blue Cross of Northeastern 	<p>Above</p>	<p>All single state and regional companies cover the procedure with the exception of BCBS FL</p>	<p>All single state and or regional companies mirror the same coverage criteria for BCBSA http://www.bcbs.com/</p>
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	Covered Lives	Hip Arthroscopic/Hip Open for FAI Coverage Position	Clinical Criteria
<p>Pennsylvania</p> <ul style="list-style-type: none"> Capital Blue Cross (Central Pennsylvania) <u>Independence Blue Cross</u> (Philadelphia, Southeastern Pennsylvania) Blue Cross Blue Shield of Rhode Island Blue Cross Blue Shield of South Carolina] Blue Cross Blue Shield of Tennessee Blue Cross Blue Shield of Vermont Blue Cross Blue Shield of Wyoming <p>United Healthcare Group</p>	75 MM+	Covered	All United Healthcare Gp Products mirror the same criteria found here. https://www.unitedhealthcareonline.com/b2c/CmAction.do?channelId=c94e74bc62c010VgnVCM100000c520720a
<ul style="list-style-type: none"> <u>AmeriChoice</u> <u>Ovations</u> <u>Oxford</u> <u>Golden Rule</u> <u>PacifiCare</u> <u>UHG International</u> <u>UnitedHealth care</u> <u>Mid Atlantic Medical Services LLC (MAMSI)</u> <p>Humana Inc.</p>	11.5MM+	Covered	http://www.humana.com/
<p>CIGNA</p>	11.4MM	Covered	http://www.cigna.com/customer_care/healthcare_professional_coverage_positions/

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Aetna, Inc.	17.4MM	Not Covered	http://www.aetna.com/healthcare-professionals/policies-guidelines/cpb_alpha.html
Health Net, Inc.	13.9MM	Covered	https://www.healthnet.com/portal/content.do?mainResourceFile=/content/general/unprotected/html/national/medical_policies.html
Harvard Pilgrim Healthcare	1.1MM	Covered	https://www.harvardpilgrim.org/portal/page?pageid=253.41628&dad=portal&schema=PORTAL
Life Wise Health Plan of Oregon, WA, AK	1.5MM	Covered	https://www.lifewiseor.com/1wor/groups/public/documents/xcpproject/pmp_Disclaimer.asp
Presbyterian Healthcare	400K	Covered	http://www.phs.org/phs/index.htm
WPS & Tricare	4.5M	Covered	http://www.wpsic.com/
NCHC-NC Medicaid	1.3MM	Covered	http://www.ncdhhs.gov/dma/hcomp/NCHC-Arthroscopic-Surgery-Policy.pdf
WA State Medicaid Plan	1.2 MM	Covered	http://hrsa.dshs.wa.gov/rbrvs/
WA Department of Labor Industries	N/A	Covered	http://www.ini.wa.gov/ClaimsIns/Files/ProviderPay/FeeSchedules/2010FS/fsSurg.pdf



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August 17, 2011

Mrs. Leah Hole-Curry
Washington State Health Care Authority
P.O. Box 42682
Olympia, WA 98504-2682

Dear Mrs. Hole-Curry,

The Health Technology Assessment entitled Hip Surgery Procedures for Femoroacetabular Impingement Syndrome (FAI) was read with interest. It is a voluminous document that reflects much work. Unfortunately, for numerous reasons, it inaccurately and incompletely reflects current clinically relevant medical science regarding patient care for FAI.

As physicians, our interest and responsibility are what is best for the patient. Some of this is lost in the HTA document. Attached is a position statement on FAI adopted by the Arthroscopy Association of North America. I hope you will find this to be clear, concise and to the point in reference to the latest and most complete medical evidence on FAI as it relates to patient care.

The HTA should be congratulated on their efforts. Perhaps the intention of this report can serve as a useful sounding board for continued efforts at patient advocacy.

Most sincerely,

J. W. Thomas Byrd, MD
Second Vice-President

JWTB/ss

enc.

Arthroscopy Association of North America Position Statement

Femoroacetabular Impingement

Femoroacetabular Impingement (FAI) is a well-recognized pathologic condition of the hip. While the etiology and natural history of the disorder are not fully understood, the pain, loss of motion and disability associated with FAI has led to significant educational activities regarding treatment. It is understood that FAI can be the cause of progressive damage to the hip joint, manifested by pain and the development of early-onset osteoarthritis.

The surgical correction of FAI is a well-founded procedure with the significant benefits of decreasing pain and improving function. It requires thoughtful patient selection and careful attention to the details of the procedure. The efficacy of the arthroscopic surgical treatment of FAI is documented in numerous studies in the peer review literature, while no studies refute its value.¹⁻³⁵ Also, there is no evidence that protracted non-operative treatment of FAI is a preferable approach for persistently symptomatic individuals.

In 2010, the RBRVS Update Committee (RUC) of the AMA approved three CPT codes for procedures that treat FAI pathology. The criteria for RUC approval is strict and stipulates that to be awarded a CPT code, a procedure must:

- have received approval from the Food and Drug Administration (FDA) for the specific use of devices or drugs;
- be a distinct service performed by many physicians/practitioners across the United States;
- be well established with outcomes documented in U.S. peer review literature;
- be neither a fragmentation of an existing procedure/service nor currently reportable by one or more existing codes.

AANA supports the role of surgical treatment of FAI. This support is based on a compelling body of evidence reflected in the scientific literature on this subject.

AANA believes that if a service or procedure has a Category I CPT code, it is by definition neither experimental nor investigational. Therefore, payers should not deny reimbursement for these services and procedures when they are medically necessary³⁶ by claiming that they are experimental or investigational. When payers do otherwise, they threaten the health of the public and unjustifiably interfere with the physician/patient relationship.³⁷

References

1. Bardakos NV, Vasconcelos JC, Villar RN. Early outcome of hip arthroscopy for femoroacetabular impingement: the role of femoral osteoplasty in symptomatic improvement. *J Bone Joint Surg Br.* 2008;90(12):1570–1575.
2. Beaulé PE, Le Duff MJ, Zaragoza E. Quality of life following femoral head-neck osteochondroplasty for femoroacetabular impingement. *J Bone Joint Surg Am.* 2007;89:773–779.
3. Beck M, Kalhor M, Leunig M, Ganz R. Hip morphology influences the pattern of damage to the acetabular cartilage: femoroacetabular impingement as a cause of early osteoarthritis of the hip. *J Bone Joint Surg Br.* 2005;87:1012–1018.
4. Beck M, Leunig M, Parvizi J, Boutier V, Wyss D, Ganz R. Anterior femoroacetabular impingement: part II. Midterm results of surgical treatment. *Clin Orthop Relat Res.* 2004;418:67–73.
5. Bedi A, Chen N, Robertson W, Kelly BT. The management of labral tears and femoroacetabular impingement of the hip in the young, active patient. *Arthroscopy.* 2008;24(10):1135–1145.
6. Bedi A, Zaltz I, DeLaTorre K, Kelly BT. Radiographic Comparison of Surgical Hip Dislocation and Hip Arthroscopy For Treatment of Cam Deformity in FAI. *Am J Sports Med* 2011;39(1):20S-28S.
7. Brunner A, Horisberger M, Herzog RF. Sports and recreation activity of patients with femoroacetabular impingement before and after arthroscopic osteoplasty. *Am J Sports Med.* 2009;37(5):917–922.
8. Byrd JW, Jones KS. Arthroscopic femoroplasty in the management of cam-type femoroacetabular impingement. *Clin Orthop Relat Res.* 2009;467(3):739–746.
9. Byrd JWT, Jones KS: Arthroscopic management of femoroacetabular impingement (FAI) in athletes, *Am J Sports Med*, 2011;39(1):7-13.

10. Clohisy JC, St John LC, Schutz AL. Surgical Treatment of Femoroacetabular Impingement: A Systematic Review of the Literature. *Clin Orthop Relat Res.* 2010;468(2):555-564.
11. Clohisy JC, Knaus ER, Hunt DM, Leshner JM, Harris-Hayes M, Prather H. Clinical presentation of patients with symptomatic anterior hip impingement. *Clin Orthop Relat Res.* 2009;467(3):638–644.
12. Espinosa N, Rothenfluh DA, Beck M, Ganz R, Leunig M. Treatment of femoroacetabular impingement: preliminary results of labral refixation. *J Bone Joint Surg Am.* 2006;88(5):925–935.
13. Ganz R, Gill TJ, Gautier E, Ganz K, Krugel N, Berlemann U. Surgical dislocation of the adult hip a technique with full access to the femoral head and acetabulum without the risk of avascular necrosis. *J Bone Joint Surg Br.* 2001;83:1119–1124.
14. Ganz R, Leunig M, Leunig-Ganz K, Harris WH. The etiology of osteoarthritis of the hip: an integrated mechanical concept. *Clin Orthop Relat Res.* 2008;466(2):264–272.
15. Ganz R, Parvizi J, Beck M, Leunig M, Notzli H, Siebenrock KA. Femoroacetabular impingement: a cause for osteoarthritis of the hip. *Clin Orthop Relat Res.* 2003;417:112–120.
16. Guanche CA, Bare AA. Arthroscopic treatment of femoroacetabular impingement. *Arthroscopy.* 2006;22(1):95–106.
17. Ilizaliturri VM, Jr, Nossa-Barrera JM, Acosta-Rodriguez E, Camacho-Galindo J. Arthroscopic treatment of femoroacetabular impingement secondary to paediatric hip disorders. *J Bone Joint Surg Br.* 2007;89:1025–1030.
18. Ilizaliturri VM, Jr, Orozco-Rodriguez L, Acosta-Rodriguez E, Camacho-Galindo J. Arthroscopic treatment of cam-type femoroacetabular impingement: preliminary report at 2 years minimum follow-up. *J Arthroplasty.* 2008;23(2):226–234.
19. Larson CM, Givens MR. Arthroscopic management of femoroacetabular impingement: early outcomes measures. *Arthroscopy.* 2008;24(5):540-546.
20. Larson CM, Giveans MR. Arthroscopic debridement versus refixation of the acetabular labrum associated with femoroacetabular impingement. *Arthroscopy.* 2009;25(4):369–376.
21. Laude F, Sariali E, Nogier A. Femoroacetabular impingement treatment using arthroscopy and anterior approach. *Clin Orthop Relat Res.* 2009;467(3):747–752.

22. Lavigne M, Parvizi J, Beck M, Siebenrock KA, Ganz R, Leunig M. Anterior femoroacetabular impingement: part I. Techniques of joint preserving surgery. *Clin Orthop Relat Res.* 2004;418:61–66.
23. Matsuda DK, Carlisle JC, Arthurs SC, Wierks CH, Philippon MJ. Comparative Systematic Review of the Open Dislocation, Mini-Open, and Arthroscopic Surgeries for Femoroacetabular Impingement. *Arthroscopy* 2011;27(2):252-269.
24. Murphy S, Tannast M, Kim YJ, Buly R, Millis MB. Debridement of the adult hip for femoroacetabular impingement: indications and preliminary clinical results. *Clin Orthop Relat Res.* 2004;429:178–181.
25. Naal FD, Miozzari HH, Wyss TF, Notzli HP. Surgical hip dislocation for the treatment of FAI in high-level athletes. *Am J Sports Med* 2011;39(3):544-550.
26. Ng VY, Arora N, Best TM, Pan X, Ellis TJ. Efficacy of Surgery for FAI. A Systematic Review. *Am J Sports Med* 2010;38:2337-2345.
27. Nho SJ, Magennis EM, Singh CK, Kelly BT. Outcomes after the Arthroscopic Treatment of FAI in Mixed Group of High-Level Athletes. *Am J Sports Med* 2011;39(1);14S-19S.
28. Peters CL, Erickson JA. Treatment of femoro-acetabular impingement with surgical dislocation and debridement in young adults. *J Bone Joint Surg Am.* 2006;88(8):1735–1741.
29. Philippon MJ, Weiss DR, Kuppersmith DA, Briggs KK, Hay CJ: Arthroscopic labral repair and treatment of femoroacetabular impingement in professional hockey players. *Am J Sports Med* 2010;38(1)99-104.
30. Philippon MJ, Briggs KK, Yen YM, Kuppersmith DA. Outcomes following hip arthroscopy for femoroacetabular impingement with associated chondrolabral dysfunction: minimum two-year follow-up. *J Bone Joint Surg Br.* 2009;91:16–23.
31. Reynolds D, Lucas J, Klaue K. Retroversion of the acetabulum. A cause of hip pain. *J Bone Joint Surg Br.* 1999;81:281–288.
32. Schilders E, Dimitrakopoulou A, Bismil Q, Marchant P, Cooke C. Arthroscopic treatment of labral tears in FAI: A Comparative Study of Re-Fixation and Resection with a Minimum Two-Year Follow-Up. *J Bone Joint Surg Br* 2011;93:1027-1032.
33. Siebenrock KA, Wahab KH, Werlen S, Kalhor M, Leunig M, Ganz R. Abnormal extension of the femoral head epiphysis as a cause of cam impingement. *Clin Orthop Relat Res.* 2004;418:54–60.

34. Tannast M, Goricki D, Beck M, Murphy SB, Siebenrock KA. Hip damage occurs at the zone of femoroacetabular impingement. *Clin Orthop Relat Res.* 2008;466(2):273–280.
35. Tanzer M, Noiseux N. Osseous abnormalities and early osteoarthritis: the role of hip impingement. *Clin Orthop Relat Res.* 2004;429:170–177
36. In Section 7.16 of the May 21, 2003 ‘Aetna class action law suit’ Settlement Agreement, ‘medical necessity’ is defined as “health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that area a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient’s illness, injury or disease; and (c) not primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis and treatment of the patient’s illness, injury or disease.”
37. December 2007 American Academy of Orthopaedic Surgeons Position Statement 1173. <http://www.aaos.org/about/papers/position/1173.asp>.

From: Morse, Josiah (LNI)

Sent: Wednesday, August 17, 2011 4:01 PM

To: Hole-Curry, Leah (HCA); Hammond, G. Steven (DOC); Hole-Curry, Leah (HCA); Mootz, Robert D (LNI); Franklin, Gary M. (LNI); Thompson, Jeffery MD (HCA); Dennis, Margaret (HCA); Santoyo, Denise (HCA)

Subject: Comment on FAI report

The report is comprehensive-it appears the authors have scoured the literature for all information including information from guidelines, CMS and other payers.

The result of key question 1 shows there are no gold-standard diagnostic criteria. It calls into question reporting of the accuracy information in the report especially as one study that presents proposed sensitivity, specificity, PPV and NPV is based on a group that has hip pain/condition and includes no 'normals'.

Summary to Key Q2 (p 74) does not address the question completely. Addresses questions about measures but not treatment goals.

Summary to Key Q3: no efficacy data. 3 bullets on short-term effectiveness but no summary of the overall quality of this evidence here (p 89), mention of 'case-series'. May be helpful to note the overall quality of the evidence available for short and long-term effectiveness in the summary.

P 99: If prevention of OA is a primary goal of correcting FAI it seems it is a proposed or purported or hypothesized rationale for the treatment. It appears there is no evidence to support the rationale.

Would be helpful to bullet, bold or otherwise call out the last sentence that no cost, cost-effectiveness data were found. Adding to that is the lack of efficacy and extremely weak effectiveness data making it impossible to know the value of the treatment from any perspective.

The summary tables (p 100) are helpful. Comments above apply to these as well.