

## Health Technology Clinical Committee

**Date:** November 22, 2019  
**Time:** 8:00 am – 5:00 pm  
**Location:** SeaTac Conference Center, SeaTac, WA  
**Adopted:** Pending

Meeting materials and transcript are available on the [HTA website](#).

### Draft HTCC Minutes

**Members present:** John Bramhall, MD, PhD, Gregory Brown, MD, PhD; Janna Friedly, MD; Chris Hearne, BSN, DNP, MPH; Laurie Mischley, ND, MPH, PhD; Sheila Rege, MD MPH; Seth Schwartz, MD, MPH; Mika Sinanan, MD, PhD; Kevin Walsh, MD; Tony Yen, MD

**Clinical experts:** Amy Yuen, MD, PhD; Mia Hagen, MD

### HTCC Formal Action

- 1. Call to order:** Dr. Brown, chair, called the meeting to order; members present constituted a quorum.
- 2. HTA program updates:** Josh Morse, program director, presented HTCC meeting protocols and guidelines; a high-level overview of the purpose, development, and history of the HTA program; a how-to participate in the HTCC process; upcoming topics; and a meetings calendar.
- 3. November 22, 2019 meeting minutes:** Draft minutes reviewed. Motion made and seconded to approve the minutes as written.

*Action:* Ten committee members approved the November 22, 2019 meeting minutes.

#### 4. Whole Exome Sequencing (WES):

**Clinical expert:** The chair introduced Amy Yuen, MD, PhD, Director Mary Bridge Genetics, Tacoma, WA.

**Agency utilization and outcomes:** Charissa Fotinos, MD, Deputy Chief Medical Officer, Health Care Authority, presented the state agency perspective on whole exome sequencing. Find the full presentation published with the [November 22, meeting materials](#).

**Scheduled and open public comments:** Chair called for public comments. Comments provided by:

- Sarah Clowes Candadai, MS, LCGC Seattle Children's Hospital Department of Laboratories.
- Jessie Conta, MS, CGC Seattle Children's Hospital Department of Laboratories, Director of Genetic Counseling Services for PLUGS (Patient-centered Laboratory Utilization Guidance Services).

Find all public presentations published with the [November 22, meeting materials](#).

**Vendor report/ HTCC question and answers:** Nedra Whitehead, RTI-University of North Carolina Evidence-based Practice Center presented the evidence review for Sacroiliac joint fusion. Find the full report published with the [November 22, meeting materials](#).

**Draft**

**HTCC coverage vote and formal action:**

***Committee decision***

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee decided that the current evidence on whole exome sequencing is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of the test, considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to cover with conditions whole exome sequencing for children and adults.

	Not covered	Covered under certain conditions	Covered unconditionally
Whole exome sequencing	0	10	0

***Discussion***

The committee reviewed and discussed the available information and limitations of the evidence base. A majority of committee members found the evidence sufficient to determine that whole exome sequencing is more effective in some scenarios and equally safe to other similar tests. In drafting the conditions for coverage, the committee recognized a need for more information and refinement of the proposed coverage criteria. Agency staff were directed to compile the information and provide the committee a draft for consideration at the next meeting scheduled for January 17, 2020.

***Limitations***

N/A

***Action***

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no Medicare NCD for whole exome sequencing.

The committee also checked for the availability of clinical guidelines. Two guidelines were identified and discussed.

As noted the committee chair directed agency staff to prepare address the need for more specificity in the proposed criteria for whole exome sequencing to be considered by the committee at the next meeting.

**5. Hip surgery for femoroacetabular impingement syndrome:**

Clinical expert: The chair introduced Mia S. Hagen, MD, University of Washington Center for Pain Relief and Professor of Anesthesiology and Pain Medicine, University of Washington School of Medicine.

**Agency utilization and outcomes:** Shana Johnson, MD, Health Care Authority; presented the state agency perspective on hip surgery for femoroacetabular impingement syndrome. Find the full presentation published with [November 22, meeting materials](#).

**Scheduled and open public comments:** The chair called for public comments. No comments were provided.

**Draft**

**Vendor report/ HTCC question and answer:** Erika Brodt, Aggregate Analytics, Inc. presented the evidence review for hip surgery for femoroacetabular impingement syndrome. Find the presentation published with the [November 22, meeting materials](#).

**HTCC coverage vote and formal action:**

***Committee decision***

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee decided that the current evidence on hip surgery for femoroacetabular impingement syndrome is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of hip surgery for femoroacetabular impingement syndrome. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover hip surgery for femoroacetabular impingement syndrome.

	Not covered	Covered under certain conditions	Covered unconditionally
Hip surgery for femoroacetabular impingement syndrome	8	2	0

***Discussion***

The committee reviewed and discussed the available studies for use of hip surgery for FAI. The discussion focused on studies available since the original review in 2011. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A clinical expert member provided detailed insight and discussion points. A majority of committee members found the evidence sufficient to determine that use of hip surgery for FAI was less safe or unproven for safety and less cost-effective or unproven for cost-effectiveness. The committee prospective on the efficacy of hip surgery for FAI was evenly divided between unproven and more effective in some cases.

***Limitations***

N/A

***Action***

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no Medicare national or local coverage determination for surgical treatment of FAI.

No new evidence-based clinical guidelines were identified for this review. The original review included a guideline from the National Institutes for Health and Clinical Excellence (NICE) for arthroscopic and open hip surgery. This guideline had not been updated since the original review (2011). The committee discussed two identified expert consensus documents (not formal guidelines) for FAI from the following organizations:

- The Warwick Agreement

**Draft**

- Lynch systematic review, 2019

There are no current or new guidelines for the HTCC to compare for consistency with their determination.

The committee chair directed HTA staff to prepare a findings and decision document on hip surgery for FAI for public comment, to be followed by consideration for final approval at the next public meeting.

**6. Meeting adjourned**

**Health Technology Clinical Committee  
DRAFT Findings and Decision**

**Topic:** Femoroacetabular Impingement Syndrome – Re-review  
**Meeting Date:** November 22, 2019  
**Final Adoption:** Pending

Meeting materials and transcript are available on the [HTA website](#).

**Number and coverage topic:**

**20190517A** – Hip Surgery for Femoroacetabular Impingement Syndrome – Re-Review

**HTCC coverage determination:**

Hip surgery for femoroacetabular impingement syndrome is not a covered benefit.

**HTCC reimbursement determination:**

**Limitations of coverage:**

N/A

**Non-covered indicators:**

Hip surgery for femoroacetabular impingement syndrome.

**Agency contact information:**

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

**Draft**

**HTCC coverage vote and formal action:**

***Committee decision***

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments and state agency utilization information. The committee decided that the current evidence on hip surgery for femoroacetabular impingement syndrome (FAI) is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of FAI. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover hip surgery for FAI.

	Not covered	Covered under certain conditions	Covered unconditionally
Hip surgery for femoroacetabular impingement syndrome	8	2	0

***Discussion***

The committee reviewed and discussed the available studies for use of hip surgery for FAI. The discussion focused on studies available since the original review in 2011. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A clinical expert member provided detailed insight and discussion points. A majority of committee members found the evidence sufficient to determine that use of hip surgery for FAI was less safe or unproven for safety and less cost-effective or unproven for cost-effectiveness. The committee prospective on the efficacy of hip surgery for FAI was evenly divided between unproven and more effective in some cases.

***Limitations***

N/A

***Action***

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no Medicare national or local coverage determination for surgical treatment of FAI.

No new evidence-based clinical guidelines were identified for this review. The original review included a guideline from the National Institutes for Health and Clinical Excellence (NICE) for arthroscopic and open hip surgery. This guideline had not been updated since the original review (2011). The committee discussed two identified expert consensus documents (not formal guidelines) for FAI from the following organizations:

- The Warwick Agreement
- Lynch systematic review, 2019

**Draft**

The committee chair directed HTA staff to prepare a findings and decision document on hip surgery for FAI for public comment, to be followed by consideration for final approval at the next public meeting.

**Health Technology Clinical Committee Authority:**

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.

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**Draft**





## Hip surgery for femoroacetabular impingement syndrome

Draft findings and decision  
Timeline, overview and comments

The Health Technology Assessment (HTA) program received one comment in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on hip surgery for femoroacetabular impingement syndrome.

### Timeline

Phase	Date	Public Comment Days
<b>Technology recommendations published</b>	March 5, 2018	
Public comments	March 5 to 19, 2018	<b>15</b>
<b>Selected technologies published</b>	March 23, 2018	
Public comments	March 23 to April 23, 2018	<b>32</b>
<b>Draft key questions published</b>	May 28, 2019	
Public comments	May 28 to June 11, 2019	<b>14</b>
<b>Final key questions published</b>	June 1, 2019	
<b>Draft report published</b>	September 5, 2019	
Public comments	September 5 to October 4, 2019	<b>30</b>
<b>Final report published</b>	October 23, 2019	
<b>Public meeting</b>	November 22, 2019	
<b>Draft findings &amp; decision published</b>	December 13, 2019	
Public comments	December 13 to 31, 2019	<b>19</b>
<b>Total</b>		<b>110</b>

### Overview

Category	Comment Period	
	<i>December 13 to 31, 2019</i>	Cited Evidence
Patient, relative, and citizen	1	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	0	0
Professional society & advocacy organization	0	0
<b>Total</b>	<b>1</b>	<b>0</b>

Comments

	Respondents	Representing	Cited Evidence
<input type="checkbox"/>	1. Reece Garrett		No

[REDACTED]

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**From:** Reece Garrett [REDACTED]  
**Sent:** Monday, December 30, 2019 5:48 PM  
**To:** HCA ST Health Tech Assessment Prog  
**Subject:** Femoroacetabular impingement (FAI) syndrome

Your recent decision to continue denying claims for FAI is an unethical cost saving measure at the expense of Washington State employees. Surgical treatment for FAI is proven and medically necessary when proper patient selection criteria such as absence of advanced osteoarthritis are met . To suggest that there are no circumstances under which this is a medically necessary treatment goes against over a decade of medical research and clinical outcomes. This decision puts the Washington Health Care Association in a shrinking minority of health care providers that refuse to recognize importance of treating FAI. Regence, Atena, HuUnitedHealthCare, Humana, Cigna, and other major insurers all deem FAI surgery efficacious and medically necessary when patient criteria are met. In light of this overwhelming recognition from other, larger, health care insurers the HCA's decision seems to be little more than health care rationing.

Understand that your decision condemns some of your members to either a life of pain and disability or premature and unnecessary hip replacement. I plan to make this a public issue and shine a light on what is obviously a means to increase your bottom line at the expense of your members.



## Hip surgery for femoroacetabular impingement syndrome – re-review

### HTCC final approval of coverage decision

(From page 7 of decision aide)

#### Next step: Proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

- Based on public comment was evidence overlooked in the process that should be considered?
- Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

#### Next step: Final determination

Following review of the proposed findings and decision document and public comments:

#### Final vote

- Does the committee approve the Findings and Decisions document with any changes noted in discussion?

**If yes**, the process is concluded.

**If no**, or unclear outcome (i.e., tie), chair will lead discussion to determine next steps.



## **Key Questions and Background**

### **Femoroacetabular impingement syndrome – re-review**

#### **Background:**

Femoroacetabular impingement (FAI) results from abnormal morphology of the acetabulum and femoral head/neck resulting in abnormal contact between the proximal femur and acetabulum during the end range of hip motion, particularly flexion and internal rotation. There are two types of FAI: cam impingement (non-spherical femoral head or abnormality at the head-neck junction) and pincer impingement (deep or retroverted acetabulum resulting in overcoverage of the femoral head). Clinically, patients frequently present with a combination of both types. Morphologic characteristics of FAI and labral tears on radiographs in asymptomatic patients appear to be common.<sup>1</sup> Abnormal contact between the femur and acetabulum may result in impingement and pain and/or reduced function; this may depend on activity level. Repetitive motion, particularly vigorous motion may result in joint and labral damage. A recent consensus document has suggested that the term femoroacetabular impingement syndrome (FAIS) be used for symptomatic presentation of FAI.<sup>2</sup> There is mixed evidence linking FAI to later development of osteoarthritis (OA)<sup>4</sup>; some studies suggest that cam lesions may be linked to OA development, but the impact of pincer lesions is less clear.<sup>3,5</sup> One recent study reported no difference in the risk of OA progression between patients with FAI and those with normal hip morphology.<sup>6</sup>

Initial management of FAI/FAIS usually is non-operative. Proponents believe that surgical correction of the impinging deformities will alleviate the symptoms and retard the progression of OA degeneration. Surgical options to correct FAI include arthroscopy, open dislocation of the hip and arthroscopy combined with a mini-open approach. The purpose of the surgery is to remove abnormal outgrowths of bone and damaged cartilage, and to reshape the femoral neck to ensure that there is sufficient clearance between the rim of the acetabulum and the neck of the femur.

While the understanding of the etiology, history and clinical presentation of FAI/FAIS has evolved, the causes of hip pain, the natural history of FAI and its relationship to osteoarthritis remain unclear. The case definition and selection criterion of patients for surgery has historically been unclear. Furthermore, questions remain about the efficacy and effectiveness, safety and cost effectiveness of hip surgery for FAIS.

#### **Policy context/reason for selection:**

This topic was originally reviewed in 2011. It is being re-reviewed in 2019 due to newly available published evidence.

#### **Objectives**

The aim of this report is to update the 2011 HTA on Hip Surgery Procedures for the Treatment of Femoroacetabular Impingement Syndrome (FAIS) by systematically reviewing, critically appraising and analyzing new research evidence comparing the safety and efficacy of operative procedures for the

treatment of FAI/FAIS compared with non-operative treatments. Information on case definition/diagnostic criteria for FAI/FAIS and validated outcomes measures from the original report will be updated as contextual questions.

## **Key Questions**

### **Contextual questions:**

Is there updated information published subsequent to the 2011 report regarding a consistent or agreed upon case definition for FAI/FAIS? Are there additional/new validated outcomes measurement instruments used for evaluation of function or pain in FAIS patients in the updated evidence base? Is there information on clinically meaningful improvement for new validated measures used in the evidence base?

### **Research key questions:**

The focus of this report is on the comparison of surgical intervention for Femoroacetabular Impingement/Femoroacetabular Impingement Syndrome (FAI/FAIS) versus non-operative treatments. When used in patients with FAI/FAIS:

#### **Key Question 1:**

What is the evidence of efficacy and effectiveness of hip surgery (open or arthroscopic) compared with non-operative treatment for FAI/FAIS? Including consideration of short-term ( $\leq 5$  years) intermediate-term ( $>5$  years to  $<10$  years) and long-term ( $\geq 10$  years) outcomes.

#### **Key Question 2:**

What is the evidence of the safety of hip surgery for FAI/FAIS compared with non-operative treatment?

#### **Key Question 3:**

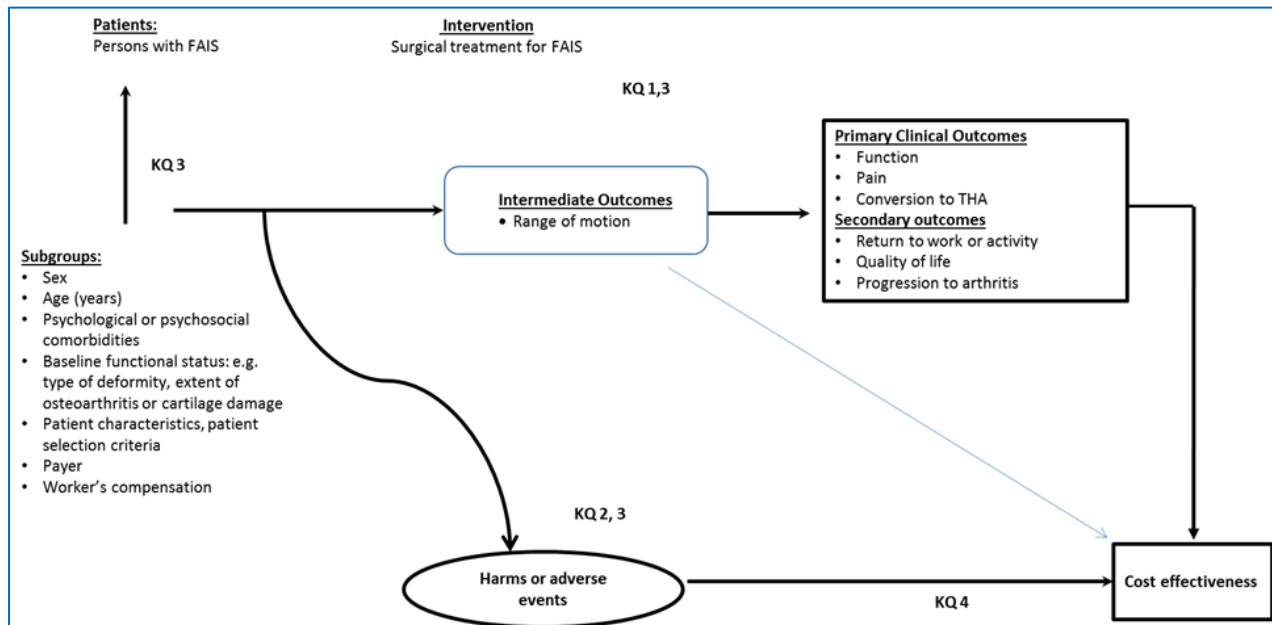
What is the evidence that hip surgery for FAI/FAIS compared with non-operative treatment has differential efficacy or safety in subpopulations (e.g. age, sex, psychological or psychosocial comorbidities, baseline characteristics, deformity type, degree of osteoarthritis or cartilage damage, provider type, payer type)?

#### **Key Question 4:**

What is the cost-effectiveness of surgery for FAI/FAIS compared with non-operative treatments in short and long-term?



**Analytic framework**



**Scope for research questions**

The report will focus on comparative studies of surgical treatment versus non-operative treatments.

**Inclusion/exclusion criteria**

Study Component	Inclusion	Exclusion
<b>Population</b>	<ul style="list-style-type: none"> <li>• Patients undergoing primary/initial treatment for FAI (any age, symptomatic or asymptomatic)</li> </ul>	<ul style="list-style-type: none"> <li>• Congenital hip dysplasia, slipped capital femoral epiphysis, Legg-Calve-Perthes</li> <li>• Studies including &lt;80% FAI/FAIS patients</li> <li>• Patients presenting for revision surgery</li> </ul>
<b>Intervention</b>	<ul style="list-style-type: none"> <li>• Operative treatment for FAI/FAIS (open, arthroscopic or combination)</li> </ul>	
<b>Comparator</b>	<ul style="list-style-type: none"> <li>• Focus: Non-operative care (activity modification, NSAIDs, injections, etc.)</li> <li>• Other: Comparison of surgical interventions (e.g. open vs. arthroscopic)</li> </ul>	
<b>Outcomes</b>	<p><b>Primary</b></p> <ul style="list-style-type: none"> <li>• Functional outcome (validated patient- and clinician-reported hip scores, validated activities of daily living)</li> <li>• Pain (validated measures)</li> <li>• Conversion To THA (“continuing” or “subsequent intervention” that is not</li> </ul>	<ul style="list-style-type: none"> <li>• Non-clinical outcomes</li> </ul>

Study Component	Inclusion	Exclusion
	<p>THA will be reported in the safety section)</p> <p><b>Secondary</b></p> <ul style="list-style-type: none"> <li>• Range of motion (intermediate)</li> <li>• Return to work or activity</li> <li>• Quality of life</li> <li>• Progression to arthritis</li> </ul> <p><b>Harms/Safety:</b></p> <ul style="list-style-type: none"> <li>• Complications/adverse events (peri-operative or longer-term)</li> <li>• Revision surgery</li> <li>• Heterotopic ossification</li> <li>• Trochanteric nonunion</li> <li>• Failure of labral re-fixation</li> <li>• Nerve damage</li> <li>• Mortality</li> </ul>	
<b>Timing</b>	<ul style="list-style-type: none"> <li>• Short- (≤5 years), intermediate- (&gt;5 years to &lt;10 years) and long-term (≥10 years)</li> </ul>	
<b>Study Design</b>	<ul style="list-style-type: none"> <li>• High quality (low risk of bias) comparative studies (e.g., randomized controlled trials, prospective observational studies) will be considered for questions 1-3. The report will focus on comparative studies.</li> <li>• Case series with ≥ 50 patients that are designed specifically to evaluate safety or comprehensive systematic reviews specifically on safety will be considered for inclusion. Case series focused on safety with fewer patient may be considered for rare outcomes</li> <li>• Full economic studies for question 4</li> </ul>	<ul style="list-style-type: none"> <li>• Non-clinical studies</li> <li>• Case reports</li> <li>• Case series designed specifically for safety with &lt;50 patients</li> <li>• Case series not specifically designed to evaluate safety</li> <li>• Imaging studies</li> </ul>
<b>Publication</b>	<ul style="list-style-type: none"> <li>• Studies published in English in peer reviewed journals, technology assessments or publically available FDA reports</li> <li>• Studies published subsequent to the 2011 report</li> <li>• For question 4 full, formal economic analyses (e.g., cost-effectiveness, cost-utility studies) published in English in a peer reviewed journal</li> </ul>	<ul style="list-style-type: none"> <li>• Abstracts, editorials, letters</li> <li>• Duplicate publications of the same study that do not report different outcomes or follow-up times</li> <li>• Single reports from multicenter trials</li> <li>• White papers</li> <li>• Narrative reviews</li> <li>• Articles identified as preliminary reports when full results are published in later versions</li> <li>• Incomplete economic evaluations such as costing studies</li> </ul>

FAI/FAIS = femoroacetabular impingement/femoroacetabular impingement syndrome; FDA = Food and Drug Administration; NSAIDs = non-steroidal anti-inflammatory drugs; THA = total hip arthroplasty.

## **References**

1. Frank JM, Harris JD, Erickson BJ, et al. Prevalence of Femoroacetabular Impingement Imaging Findings in Asymptomatic Volunteers: A Systematic Review. *Arthroscopy* 2015;31:1199-204.
2. Griffin DR, Dickenson EJ, O'Donnell J, et al. The Warwick Agreement on femoroacetabular impingement syndrome (FAI syndrome): an international consensus statement. *Br J Sports Med* 2016;50:1169-76.
3. Kuhns BD, Weber AE, Levy DM, Wuerz TH. The Natural History of Femoroacetabular Impingement. *Front Surg* 2015;2:58.
4. Murphy NJ, Eyles JP, Hunter DJ. Hip Osteoarthritis: Etiopathogenesis and Implications for Management. *Adv Ther* 2016;33:1921-46.
5. Nakano N, Khanduja V. Femoroacetabular impingement: the past, current controversies and future perspectives. *Phys Sportsmed* 2018;46:270-2.
6. Wyles CC, Heidenreich MJ, Jeng J, Larson DR, Trousdale RT, Sierra RJ. The John Charnley Award: Redefining the Natural History of Osteoarthritis in Patients With Hip Dysplasia and Impingement. *Clin Orthop Relat Res* 2017;475:336-50.



Washington State Health Care Authority, HTA Program  
Final Key Questions

**Hip Surgery procedures for treatment of femoroacetabular impingement**

**Introduction**

HTA has selected hip surgery procedures for the treatment of femoroacetabular impingement (FAI) to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input on all available evidence. HTA published the Draft Key Questions to gather public input about the key questions and any additional evidence to be considered in the evidence review. Key questions guide the development of the evidence report. HTA seeks to identify the appropriate topics (e.g. population, indications, comparators, outcomes, policy considerations) to address the statutory elements of evidence on safety, efficacy, and cost effectiveness relevant to coverage determinations.

Femoroacetabular impingement is a condition where friction in the hip joint caused by the ball and socket rubbing causes wear or damage to the cartilage, which is thought to cause pain and contribute to the development of osteoarthritis. Hip surgery is a treatment aimed at correction of the abnormal hip biomechanics causing the friction in order to prevent or delay osteoarthritis and relieve pain.

***Final Key Questions***

When used in patients with Femoroacetabular Impingement (FAI):

1. What is the case definition of FAI, and are there measures of reliability and validity for case identification?
2. What are the expected treatment outcomes of hip surgery for FAI, and are there validated instruments and scores to measure clinically meaningful improvement?
3. What is the evidence of efficacy and effectiveness of hip surgery (open or arthroscopic) for FAI? Including consideration of short term and long term:
  - a. Development or progression of Osteoarthritis
  - b. Impact on Function, Pain, range of motion, quality of life, activities of daily living and return to work
  - c. Need for continuing and/or subsequent intervention
  - d. Other reported measures
4. What is the evidence of the safety of hip surgery for FAI? Including consideration of:
  - a. Adverse events type and frequency (peri-operative, cartilage damage, fractures, nerve damage, mortality, other major morbidity)
  - b. Revision/re-operation rates (if not addressed in efficacy)

5. What is the evidence that hip surgery for FAI has differential efficacy or safety issues in sub populations? Including consideration of:
  - a. Gender
  - b. Age
  - c. Psychological or psychosocial co-morbidities
  - d. Baseline functional status: e.g. type of deformity, extent of osteoarthritis or cartilage damage
  - e. Other patient characteristics or evidence based patient selection criteria, especially comorbidities of diabetes and high BMI
  - f. Provider type, setting or other provider characteristics
  - g. Payor/ beneficiary type: including worker's compensation, Medicaid, state employees
  
6. What evidence of cost implications and cost-effectiveness of hip surgery for FAI? Including consideration of:
  - a. Costs (direct and indirect) and cost effectiveness
  - b. Short term and long term

***Policy Context:***

Osteoarthritis (OA) is very common, and affects some 27 million Americans; and is characterized by the breakdown of cartilage – the part of a joint that cushions the ends of the bones and allows easy movement. As cartilage deteriorates, bones begin to rub against one another. OA can also damage ligaments, menisci, and muscles and may cause bone outgrowths. Symptoms of OA vary greatly: some patients have minor to debilitating pain, swelling and stiffness. Other patients have few symptoms in spite of significant degeneration. The causes of hip pain and OA, and factors for progression and impact are not fully understood. OA is thought to be primarily related to aging (Primary OA) or severe congenital or developmental deformities (Secondary OA); though repetitive use; injury; weight; and heredity may play a role. There is no treatment to stop cartilage degeneration or repair damaged cartilage. The goal of treatment for patients with symptoms is to reduce joint pain and inflammation while improving and maintaining joint function.

Femoroacetabular impingement (FAI) syndrome is a recently recognized diagnosis in primarily younger individuals where relatively minor abnormalities in the joint (orientation or morphology) are thought to cause friction/impingement and pain. It is theorized that FAI starts the breakdown of cartilage, leading to OA. There are two types of FAI: cam impingement (most common in young athletic males) and pincer impingement (most common in middle-aged women). Proponents believe that surgical correction of the impinging deformities will alleviate the symptoms and retard the progression of OA degeneration.

***Technology Description:***

Hip surgery is an invasive procedure to correct FAI using either an open surgery or arthroscopic approach. The surgeon cuts off abnormal outgrowths of bone, removes damaged cartilage, and reshapes the femoral neck to ensure that there is sufficient clearance between the rim of the joint socket and the neck of the femur. After

corrective surgery, avoidance of weight bearing for several weeks to months and rehabilitation is required.

**Issues:**

The causes of hip pain, the natural history of FAI and its relationship to osteoarthritis are unclear; case definition and the selection criterion of patients for this procedure is uncertain.

Significant questions remain about the safety, efficacy and effectiveness and cost effectiveness of hip arthroplasty for FAI. Effectiveness questions particularly center on whether the potential beneficial outcomes of long term pain and functional improvement, and prevention of a total hip replacement due to OA deterioration occur with this surgical intervention; the risks of the intervention, and how often complications arise.





## Whole exome sequencing: draft coverage criteria

### Covered with conditions

#### Criteria

Whole exome sequencing (WES) is considered medically necessary for the evaluation of unexplained congenital or neurodevelopmental disorders in a phenotypically affected individual when **ALL of the following** criteria are met:

1. A board-certified or board-eligible Medical Geneticist, or an Advanced Practice Nurse in Genetics (APGN) credentialed by either the Genetic Nursing Credentialing Commission (GNCC) or the American Nurses Credentialing Center (ANCC), who is not employed by a commercial genetic testing laboratory, has evaluated the patient and family history, and recommends and/or orders the test; and
2. A genetic etiology is considered the most likely explanation for the phenotype, based on **EITHER of the following**; and
  - Multiple abnormalities affecting unrelated organ systems, (e.g. multiple congenital anomalies); or
  - **TWO of the following criteria are met:**
    - Significant abnormality affecting at minimum, a single organ system,
    - Profound global developmental delay<sup>1</sup>, or intellectual disability<sup>2</sup> as defined below,
    - Family history strongly suggestive of a genetic etiology, including consanguinity,
    - Period of unexplained developmental regression (unrelated to autism or epilepsy),
    - Biochemical findings suggestive of an inborn error of metabolism where targeted testing is not available;
3. Other circumstances (e.g. environmental exposures, injury, infection) would not reasonably explain the constellation of symptoms; and
4. Clinical presentation does not fit a well-described syndrome for which single-gene or targeted panel testing (e.g., comparative genomic hybridization [CGH]/chromosomal microarray analysis [CMA]) is available; and
5. The differential diagnosis list and/or phenotype warrant testing of multiple genes and **ONE of the following**:
  - WES is more efficient and economical than the separate single-gene tests or panels that would be recommended based on the differential diagnosis (e.g., genetic conditions that demonstrate a high degree of genetic heterogeneity); or
  - WES results may preclude the need for multiple invasive procedures or screening that would be recommended in the absence of testing (e.g. muscle biopsy);
6. A diagnosis cannot be made by standard clinical work-up; and

7. Results will impact clinical decision-making for the individual being tested; and
8. Pre- and post-test counseling by an American Board of Medical Genetics or American Board of Genetic Counseling certified genetic counselor.

**Not medically necessary for:**

- Uncomplicated autism spectrum disorder, developmental delay, mild to moderate global developmental delay.
- Other circumstances (e.g. environmental exposures, injury, infection) that reasonably explain the constellation of symptoms.
- Reducing diagnostic uncertainty.
- Carrier testing for “at risk” relatives.
- Prenatal or pre-implantation testing.

**Definitions:**

<sup>1</sup> **Global developmental delay (GDD)** is used to categorize children who are younger than five years of age.

**GDD** is defined as a significant delay<sup>2</sup> in two or more developmental domains, including gross or fine motor, speech/language, cognitive, social/personal, and activities of daily living and is thought to predict a future diagnosis of ID. Such delays require accurate documentation by using norm-referenced and age appropriate standardized measures of development administered by experienced developmental specialists, or documentation of profound delays based on age appropriate developmental milestones are present.

*Reference: Comprehensive Evaluation of the Child With Intellectual Disability or Global Developmental Delays Pediatrics 2014;134:e903–e918. Page e905*

**Significant delay** is typically defined as performance two standard deviations or more below the mean on age-appropriate, standardized, normal-referenced testing.

<sup>2</sup> **Intellectual disability (ID)** is a life-long disability diagnosed at or after age five when intelligence quotient (IQ) testing is considered valid and reliable. The Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association (DSM-V), defines patients with ID as having an IQ less than 70, onset during childhood, and dysfunction or impairment in more than two of areas of adaptive behavior or systems of support.