

July 5, 2018

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**Subject: Draft Key Questions for Health Technology Assessment (HTA) Program
Review of Sacroiliac Joint Fusion**

Dear Mr. Morse:

On behalf of the American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), AANS/CNS Joint Section on Disorders of Spine and Peripheral Nerves (DSPN) and Washington State Association of Neurological Surgeons (WSANS), we appreciate the opportunity to provide feedback on the draft key questions for evidence review for sacroiliac (SI) joint fusion. In our estimation, the draft questions are generally reasonable and appropriate for the evaluation of efficacy, safety and cost of SI joint fusion procedures. However, we offer the comments below regarding some of the specifics proposed to assess the procedure.

Efficacy Questions

Efficacy question 1 (EQ 1). What is the effectiveness and comparative effectiveness of sacroiliac joint fusion surgery on health outcomes?

Question EQ 1 refers to effectiveness of SI joint fusion on health outcomes. Outcomes include pain, function, quality of life (QOL), patient satisfaction, opioid use and return to work. These outcome measures are all used in the available randomized controlled trials (RCTs) for SI joint fusion and represent readily quantifiable outcome measures. We feel these are appropriate.

Efficacy question 1a (EQ 1a). What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate efficacy outcomes?

Question EQ 1a asks about comparative effectiveness for intermediate outcomes. Proposed outcomes include length of stay and non-union. Fusion rate may be a good intermediate outcome measure to investigate for SI joint fusion. Fusion status at a certain time point could correlate with the long-term

outcomes and is worth investigating. Length of stay seems problematic as an intermediate outcome measure, as there are many variables outside of surgery and patient function that can contribute to a longer hospital stay without necessarily compromising the long-term effectiveness of surgery, including comorbidities and minor complications. Length of stay may be more relevant as a safety measure to assess the general morbidity of the surgery, but seems inappropriate as an efficacy measure. A better measure may be post-operative referral to an acute or subacute rehabilitation facility. A patient who meets discharge criteria for home is more functional than a patient who requires post-operative rehabilitation and, therefore has an increased likelihood for a better long-term outcome.

Safety Questions

Safety question 1 (SQ 1). What is the safety of sacroiliac joint fusion surgery?

SQ 1 concerns the safety of SI joint fusion. Safety measures include rates of infection, serious adverse events and surgical morbidity. These rates of complications all seem reasonable as basic measures of safety.

Safety question 1a (SQ 1a). What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate safety outcomes?

SQ 1a asks about comparative effectiveness on intermediate safety outcomes including intraoperative blood loss and duration of surgery. These also seem reasonable as assessments of the relative morbidity of a procedure and possibly correlate with rates of adverse events.

Cost Questions

Cost question 1 (CQ 1). What is the cost and cost-effectiveness of sacroiliac joint fusion surgery?

CQ 1 seems fairly straight forward with assessment of cost and cost per QOL-adjusted life years gained. These costs must be put in perspective in comparison to the costs of continued non-surgical interventions as well as the opportunity cost of lost productivity in those patients with disability recalcitrant to non-surgical therapy.

Contextual Questions

Contextual Question 1. What are the recommended ways to diagnose SI joint pain or disruption, and what is the accuracy of various diagnostic tests?

We understand that the contextual questions will not be part of the systematic review for SI joint fusion. Nevertheless, an examination of the tests used to diagnose and appropriately select patients is vital to consider for any treatment. The first question regarding recommended ways to diagnose SI joint pain and relative accuracy of diagnostic tests is important to study to further enhance the reliability of establishing a diagnosis of SI joint dysfunction.

Contextual Question 2. What is known about the frequency of various diagnostic approaches to SI joint pain or disruption in usual clinical practice?

The second contextual question seems less important in determining the utility of the procedure itself but could be helpful in determining how frequently an average clinician will initiate a diagnostic process for SI joint symptoms and give an idea of prevalence of these symptoms.

Process Concerns

We are concerned that a 14 day comment period for draft key questions is not long enough. Although in the particular case of SI joint fusion, we believe the draft key questions are generally appropriate, this is not always the case and limiting the comment period to two weeks, particularly over a major national holiday, does not permit adequate time for a thorough vetting. Organized neurosurgery has been active in reviewing, commenting upon and attending meetings regarding procedures under consideration by the HTA program for over a decade. We urge the Washington State Health Care Authority to allow more time for stakeholders to review and respond to draft documents posted for coverage policy considerations. We also ask for consideration of national holidays when setting a deadline for a response.

Conclusion

We appreciate the opportunity to review and comment upon the draft key question that will be used in the development of the evidence review for SI Joint Fusion. The key questions are generally reasonable and we look forward to the opportunity to comment on the draft evidence report in October.

Thank you for considering our comments.

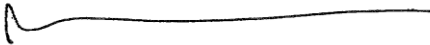
Sincerely,



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