Comments on Oregon Health Authority's Health Evidence Review Commission's Draft Coverage Guidance *Corticosteroid Injections – Low Back Pain*

December 8, 2016

Representatives of the 11 undersigned medical specialty societies, comprising physicians who utilize and/or perform spinal injection procedures to accurately diagnose and treat patients suffering from spine pathologies, would like to take this opportunity to comment on Health Evidence Review Commission's (HERC) draft coverage guidance *Corticosteroid Injections – Low Back Pain.*

We are disappointed to see that the report is almost entirely based on a flawed systematic review. (1) As discussed in letters submitted to Oregon Health Authority/HERC in January and May of 2016, this review arrived at erroneous conclusions due to a significantly flawed methodology, which included studies with poor patient selection criteria (e.g. nonspecific diagnoses, varying symptom duration, psychosocial comorbidities); technical limitations (e.g. non-standardized procedures); and lack of categorical outcomes data. We extend an offer to HERC, as we have several times this year, to provide clinical expertise in reviewing the evidence. A 1,000-word restriction precludes a comprehensive assessment; however we encourage HERC to review a critique of the Agency for Healthcare Research and Quality's (AHRQ) review published in a peer-reviewed journal. (2) It is important that HERC carefully consider the AHRQ report's flaws. A coverage guidance based upon a biased assessment of the evidence does a disservice to all stakeholders. This will result in egregious denial of access to procedures that truly can help patients. In the absence of access to interventional pain procedures, patient outcomes will include: unnecessary suffering, additional drug dependency, unnecessary surgeries, increased utilization of more expensive therapies, and additional work disability. The aforementioned will result in the delivery of lower quality medical care and contribute to greater consumption of healthcare resources.

Effectiveness of Corticosteroid Injections

The AHRQ report, and by extension the HERC's coverage guidance, has arrived at erroneous conclusions. They relied on flawed randomized controlled trials (RCT), and failed to acknowledge the importance of high quality observational studies that include subgroup analyses assessing effectiveness of corticosteroid injections by specific diagnosis, use of image guidance, and technical approach. An observational trial with appropriately selected patients and treatment indications, accurate contemporary treatment techniques, and appropriate categorical outcomes measured at rational time increments is far more relevant than an RCT with improper patient and treatment indications, antiquated or poor treatment technique, and weaker outcome measures. The effectiveness of transforaminal injections of steroid, in particular, has been confirmed in several RCTs and high quality observational studies. (3-9)

Specific Diagnosis

There is no physiologic process beyond systemic effect by which steroids delivered to the epidural space would be expected to relieve axial back pain arising from nociception in the

intervertebral discs, facet joints, sacroiliac joints, or supporting musculature. There is, however, ample evidence that radicular pain has an inflammatory basis, potentially susceptible to targeted delivery of anti-inflammatory agents to the interface of neural tissue and the compressive lesion. (10) The identification of underlying pain etiologies is essential; different pathologies have varying responses to treatment and different natural histories which impact prognosis. The time frame of follow-up to determine clinical utility becomes imperative.

Image Guidance
Data show that "epidural" injections performed without image guidance may not universally reach the epidural space, even in expert hands. (11-13) Off-target medication delivery may not be efficacious and may be dangerous.

Approach/Access/Accuracy
Midline interlaminar ESIs and caudal injections may deliver medication distant from the site of pathology, without certainty that the steroid will reach, or in what concentration it will reach, the ventral epidural space. In contrast, transforaminal ESIs place the needle in direct proximity to the target nerve and verify delivery to that site by observing contrast media flow. (14) Recently described lateral parasagittal interlaminar ESIs have also been shown to preferentially deliver injectate to the target ventral epidural space. (15) It is not reasonable to combine these different injection techniques in an evaluation of "epidural steroid injections".

General Public Health Concerns, Competing Therapies
Some patients have no treatment options apart from spinal injections. Implicit in the discussion of spinal injections is that conservative care (e.g. lifestyle changes, physical therapy, medications) has failed. Surgery can be contraindicated due to comorbidites or age, and entails very real risks of immediate or delayed surgical failure, technical failure, serious infections, permanent paralysis, re-herniations, and subsequent segmental instability requiring fusion.

Opioid and non-opioid analgesics have limited utility with high numbers needed to treat (NNT) ranging from 4.5 to 16 (16) and significant potential for harm including death, exceeding 16,500 for NSAIDS (17) and 18,663 from prescription opiates (18). It has been estimated that at least 103,000 patients are hospitalized annually in the United States for serious gastrointestinal complications due to NSAID use. At an estimated cost of $15,000-$20,000 per hospitalization, annual direct costs of such complications exceed $2 billion. (17) By contrast, NNT for transforaminal epidural steroid injections to avoid surgery is 3, and to achieve 50% pain relief is 4. (3,4) In a meta-analysis of 26 trials, 33-50% of patients considering surgery who undergo ESI can avoid surgery. (19) Interventional procedures offer a safe alternative to opiates and an effective tool in tapering patients off of opiates. Evidence to support other "treatment options" available to patients (e.g. acupuncture, cognitive behavioral therapy, yoga) is inconsistent, weak, or non-existent. (20)

Summary
Oregon Health Authority has effectively left Oregon Health Plan patients (low-income and disabled individuals), without hope for a future without debilitating pain. Elimination of coverage contradicts coverage policies implemented by all major health plans and Medicare.

Spinal injections are not the panacea for all spinal conditions. There are conditions best treated conservatively and others best treated surgically. Spinal injections provide a valuable alternative option for some people. Unlike some medical treatments that "cure" a problem, many spinal conditions cannot be cured. Repetitive, palliative treatments may be the only option. The risk-benefit ratio of intermittent spinal injections can be preferable to perpetual use of risk-laden medications, or simply living with pain and disability.

Thank you for considering our comments regarding the safety and effectiveness of corticosteroid injections -- effective tools in the treatment of appropriately selected patients. Please contact Belinda Duszynski, Spine Intervention Society staff (bduszynski@spinalinjection.org), with questions.

Word Count: 1000

Sincerely,

American Academy of Pain Medicine

American Academy of Physical Medicine and Rehabilitation

American College of Radiology

American Society of Anesthesiologists

American Society of Neuroradiology

American Society of Regional Anesthesia and Pain Medicine

American Society of Spine Radiology

North American Neuromodulation Society

North American Spine Society

Society of Interventional Radiology

Spine Intervention Society

Comments Submitted to Oregon Health Authority on behalf of the aforementioned societies by:

Belinda Duszynski
Senior Director of Policy and Practice
Spine Intervention Society
120 E. Ogden Avenue, Suite 202
Hinsdale, IL 60521
Phone: 630.203.2252
Email: bduszynski@spinalinjection.org

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Additional references and evidence reviews available upon request.