Washington State Health Care Authority
Health Technology Assessment

Key Questions and Background

Spinal Injections – Re-review

Background

Disease

Back and neck pain are common conditions, with sixty to eighty percent of U.S. adults afflicted at some time during their life. Back pain, and then neck pain, are the most common causes of disability and loss of productivity. In most patients reporting low back pain (>85%), symptoms cannot reliably be attributed to a specific spinal disease or pathology (Chou R, Qaseem A, Owens DK, et al. Diagnostic imaging for low back pain: advice for high-value health care from the American College of Physicians. Ann Intern Med. 2011;154(3):181-9.) Some believe that a similar majority of neck pain is non-specific. Most patients' symptoms resolve satisfactorily within a relatively short time span (six weeks). In 5 – 10% of patients, pain does not satisfactorily resolve and the symptoms can be disabling and the social and economic impact of chronic pain is enormous. Discovering the cause for nonspecific low back and neck pain symptoms remains challenging. Some psychosocial risk factors for the progression to chronicity have been identified, but the origin and neurophysiologic pain sensations are poorly understood.

Treatments

Chronic pain treatment may include pharmacological treatment, physical therapy, psychological care and coping skills, exercise, education, antidepressants, cognitive behavioral therapy and supported self-management, spinal manipulations, electrical stimulation, injections, implanted devices, and other surgical treatment. Treatment strategies generally begin with the least invasive and low risk interventions and progress if the treatments are not effective. Treatment often involves a combination of interventions.

Technology

Spinal injections are not usually performed until non-surgical treatments have been given a fair trial and have not provided adequate relief. Intraspinal injections are intended to provide relief by injection of an anti-inflammatory agent (e.g. steroid); and/or anesthetic into the spine or space around the spinal nerves and joints. Intraspinal injections include epidural steroid injections, facet joint injections, medial branch block, sacroiliac joint injections and intradiscal steroid injections.

Prior Washington Health Care Authority Coverage Determination

Given that there were significant questions about the safety, efficacy and effectiveness (particularly long term), and the cost effectiveness of spinal injections, the Washington State HCA commissioned a Health Technology Assessment (HTA) on Spinal Injections and in 2011, the Health Technology Clinical Committee (HTCC) issued the following coverage determination:

Therapeutic Medial Branch Nerve Block injections, Intradiscal injections and Facet injections are not a covered benefit

Therapeutic Lumbar Epidural Injections; Cervical-thoracic Epidural Injections and Sacroiliac Joint Injections are a covered benefit for the treatment of chronic pain following certain specific conditions.

Current Situation

Since the last HTCC meeting, new literature has been identified addressing the topic. In addition, new safety concerns have emerged for epidural injections from the FDA. Therefore, the HCA selected this topic for re-review.

Objectives

The primary aim of this assessment is to update the previous review on spinal injections.

Key Questions

When used in adult patients with subacute or chronic back or neck pain:

1. What is the evidence of efficacy and effectiveness of spinal injections? Including consideration of:
    a. Short-term and long-term measures, including measures related to:
    b. repeated spinal injections multilevel spinal injections bilateral versus unilateral spinal injections
    c. Impact on clinically meaningful physical function and pain Impact on quality of life, patient satisfaction
    d. Opioid use, return to work, and any other reported surrogate measures

2. What is the evidence of the safety of spinal injections? Including:
    a. Adverse event type and frequency (mortality, major morbidity, other)
    e. Dural or arachnoid puncture
    f. Infection
    g. Epidural or intradural hematoma
    h. Allergic reaction
    i. Nerve or spinal cord injury
    j. Artery/vein damage/puncture
    k. Arachnoiditis

3. What is the evidence that spinal injections have differential efficacy or safety issues in sub populations? Including consideration of:
   a. Patient characteristics (gender, age, psychological or psychosocial co-morbidities, diagnosis, duration of pain)
   b. Injection characteristics (type of steroid [particulate, non-particulate], use of guidance, route of administrationProvider type, setting, or other provider characteristics
   c. Provider type, setting, or other provider characteristics
   d. Payer/ beneficiary type: including worker's compensation, Medicaid, state employees

4. What is the evidence of cost implications and cost-effectiveness of spinal injections? Including:
   a. Direct costs over short term and over expected duration of effect
   b. Comparative costs

Inclusion and exclusion criteria

Study Component	Inclusion	Exclusion
Participants	Adults with: ◆ Cervical or lumbar sub-acute or chronic pain with or without radiculopathy or radiculitis	◆ Children ◆ Acute major trauma ◆ Cancer ◆ Infection ◆ Cauda equina syndrome ◆ Fibromyalgia ◆ Spondyloarthropathy ◆ Osteoporosis ◆ Vertebral compression fracture
Intervention	Lumbar, sacral or cervical therapeutic spinal injections to include: ◆ Epidural injections ◆ Facet joint injections ◆ Medial branch block ◆ Sacroiliac joint injections ◆ Intradiscal injections	◆ Extraspinal injections (Botulinum toxin injections, local injections, paraspinal muscle injections, prolotherapy) ◆ Chemonucleolysis ◆ Radiofrequency denervation, intradiscal electrothermal therapy, coblation nucleoplasty and related procedures ◆ Drugs added to corticosteroids such as hyaluronidase and clonidine
Comparators	◆ Placebo or active control	◆ Spinal steroid injections
Outcomes	◆ Pain ◆ Physical function ◆ Health-related quality of life ◆ Patient satisfaction ◆ Opioid use ◆ Prevention of surgery ◆ Complications and adverse effects (e.g. procedural complications and technical failures).	◆ Non-clinical outcomes

Study Component	Inclusion	Exclusion
Study Design	◆ KQs 1 & 3: RCTs ◆ KQ 2: RCTs, observational studies with harm detection as primary purpose, and reviews of case reports of serious harms ◆ KQ 4: Formal economic studies	◆ Case series other than those with N ≥ 100 for key question 2 ◆ Case reports other than for context ◆ Non-clinical studies (e.g., technical reports) ◆ Studies in which < 75% (or an unreported percentage) of patients have any of the excluded diagnoses (see above)
Publication	◆ Studies published in English in peer reviewed journals, published HTAs or publicly available FDA reports ◆ Full formal economic analyses (e.g. cost-utility studies) published in English in an HTA, or in a peer-reviewed journal published after those represented in previous HTAs.	◆ Abstracts, editorials, letters ◆ Duplicate publications of the same study which do not report on different outcomes ◆ Single reports from multicenter trials ◆ Studies reporting on the technical aspects spinal injections ◆ White papers ◆ Narrative reviews ◆ Articles identified as preliminary reports when results are published in later versions ◆ Incomplete economic evaluations such as costing studies

Public Comment & Response

See Draft Key Questions: Public Comment and Response document published separately.