# **Tennessee Society** *of* **Interventional Pain Physicians American Society** *of* **Interventional Pain Physicians**<sup>®</sup>

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November 8, 2013

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RE: Cervical Epidural Steroid Injections for the Treatment of Pain

Dr. Willis:

On behalf of the Tennessee Society of Interventional Pain Physicians (TNSIPP) and American Society of Interventional Pain Physicians (ASIPP), we would like to thank you for publishing the updated medical policy for cervical epidural injections. However, we are very much concerned with the development of the policy and its implications of noncoverage. Consequently, we would like to provide comments with the primary objective to ensure that cervical epidural injections are provided appropriately and the patients insured by Blue Cross Blue Shield of Tennessee maintain access to care. We are hopeful that you will reconsider the policy by appropriately interpreting the evidence and reverse the proposed decision of noncoverage.

Based on an appropriate analysis of the available evidence utilizing IOM principles for preparing systematic reviews and guidelines, there is moderate to good evidence for epidural injections in managing pain of cervical origin. In recent systematic reviews by Diwan et al (1), the evidence-based guidelines by Manchikanti et al (2) based on multiple randomized controlled trials, fair to good evidence has been demonstrated in managing cervical disc herniation and radiculopathy (3-8), cervical spinal stenosis (9), cervical post surgery syndrome (10), and axial neck pain without disc herniation, radiculitis, or facet joint pain (11,12).

#### **BACKGROUND INFORMATION:**

ASIPP is a not-for-profit professional organization comprising over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States.

TNSIPP is a state organization of ASIPP with membership of over 100.

Interventional pain management is defined as the discipline of medicine devoted to the diagnosis and treatment of pain-related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment (13).

Interventional pain management techniques are minimally invasive procedures including percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves and some surgical techniques such as laser or endoscopic diskectomy, intrathecal infusion pumps and spinal cord stimulators for the diagnosis and management of chronic, persistent or intractable pain (14).

#### **EVIDENCE SYNTHESIS**

There has been a growing emphasis on evidence synthesis and development of guidelines based on systematic reviews with the Institute of Medicine (IOM) re-engineering its definition of clinical guidelines in 2011 (15). Accordingly, the new definition emphasizes that "clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternate care options." Thus, the new definition departs from a 1990 IOM report, which defined guidelines as, "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (16).

The new definition provides a clear distinction between the term "clinical practice guideline" and other forms of clinical guidance derived from widely disparate development processes, such as consensus statement, expert advice, and appropriate use criteria. In addition, the new definition also underscores systematic review and both benefits and harms assessment as essential components of clinical practice guidelines. While any group of individuals can designate itself as an evidence-based medicine, comparative effectiveness research or guideline group, they may reach different conclusions based on various interests (15). However, IOM provided guidance for trustworthy guidelines, noting that they should be:

- 1. Based on a systematic review of the existing evidence
- 2. Developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups
- 3. Considerate of important patient subgroups and patient preferences, as appropriate
- 4. Based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest
- 5. Clear in their explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations
- 6. Reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.

Appropriately developed guidelines must incorporate validity, reliability, reproducibility, clinical applicability, flexibility, clarity, development through a multidisciplinary process, scheduled reviews, and documentation (17). When appropriately applied, rigorously developed guidelines have the potential to reduce undesirable practice variation, reduce the use of services that are of minimal or questionable value, increase utilization of services that are effective, but underused, and target services to those populations most likely to benefit.

Interventional pain management is an emerging specialty. As many providers are concerned, there has been significant growth of all modalities of treatments and continuing development of evidence synthesis when compared to the lumbar spine. Cervical modalities only constitute a small proportion. Even then, appropriate utilization is essential.

In preparing guidelines and systematic reviews, it is essential to apply methodologic quality or validity assessment of all included manuscripts, rather than utilizing individual opinions. Further, this process

should be transparent and available to the public. As the policy shows for cervical epidural injections, Hayes guidelines are used as a reference. These are not available openly to the public. They are not scrutinized or peer-reviewed. Similarly, Milliman guidelines follow the same principles competing for business from industry, as well as the provider community. To subscribe to these guidelines, it costs a physician tens of thousands of dollars. Consequently, any conclusions recommended by organizations without transparency and free availability and publication in peer-reviewed journals, that lack listing on the Agency for Healthcare Research and Quality (AHRQ) National Guidelines Clearinghouse (NGC), and that are expensive to review, must be abandoned.

In grading the overall strength of evidence for an intervention, the United States Preventive Services Task Force (USPSTF) (18) has established 2 systems which classify the strength as good, fair, and limited or poor, and Grade I to III.

Grade	Definition					
Good	Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality RCTs or studies of diagnostic test accuracy).					
Fair	Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least one higher-quality trial or study of diagnostic test accuracy of sufficient sample size; 2 or more higher-quality trials or studies of diagnostic test accuracy with some inconsistency; at least 2 consistent, lower-quality trials or studies of diagnostic test accuracy or multiple consistent observational studies with no significant methodological flaws).					
Limited or Poor	Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.					

**Table 1.** Method for grading the overall strength of evidence for an intervention.

Adapted and modified from methods developed by U.S. Preventive Services Task Force (18).

**Table. 2.** Quality of evidence developed by AHRQ.

I:	Evidence obtained from at least one properly randomized controlled trial.
II-1:	Evidence obtained from well-designed controlled trials without randomization.
II-2:	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
II-3:	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
III:	Opinions of respected authorities, based on clinical experience descriptive studies and case reports or reports of expert committees.

Adapted from the Agency for Healthcare Research and Quality, U.S. Preventive Services Task Force (18).

Methodology is not the only essential criteria, but understanding the technique and unbiased assessment is essential. This should include, as stated in the USPSTF or any other methodology of strength of evidence, the exact statement rather than injection of multiple philosophies to discredit or disapprove a treatment. By the same token, it also applies in reference to the negative evidence and its inclusion by all cervical epidural injections.

Consequently, guidelines from ASIPP (2) utilizing IOM criteria of systematic reviews and guideline preparation have taken a balanced approach and showed that of all the therapeutic interventions assessed, only 52% received a grading of fair to good.

# **CERVICAL EPIDURAL INJECTIONS**

Chronic, persistent neck and upper extremity pain and radicular pain may be secondary to disc herniation, discogenic pain, spondylosis, spinal stenosis, or post cervical surgery syndrome resulting in disc-related pain with or without radiculitis.

Cervical epidural injections have been used to treat radicular pain from herniated discs, spinal stenosis, chemical discs, chronic neck pain with or without radiculitis secondary to post cervical surgery syndrome, and chronic neck pain of discogenic origin. The interlaminar approach is the most commonly applied modality in managing cervical discogenic pain.

While there are multiple systematic reviews and guidelines, recently Diwan, et al (1), in a systematic review which has been quoted in your manuscript, with literature included through December 2011, assessed the evidence with inclusion of 7 randomized trials (3,4,6-12). They showed good evidence for epidural injections in treating cervical disc herniation, and fair evidence for axial or discogenic pain without facet joint pain, central spinal stenosis, and post cervical surgery syndrome. Later, the literature search by Manchikanti et al in 2013 (2) identified additional studies; however none of them met inclusion criteria. Since the publication of "An update of comprehensive evidence-based guidelines for interventional techniques of chronic spinal pain: Part II: Guidance and recommendations" (2), there have been 2 recent publications with an update of the management of axial or discogenic pain and disc herniation (5,12).

While we will be available to provide you with detailed information, the following table shows the results of randomized trials of the effectiveness for cervical interlaminar epidural injections.

Study			Pain Relief and Function			Results			
Study	Dentisiaante	Interventions				Short	Long-term		Commont(s)
Characteristics	rarticipants	interventions	3 mos.	6 mos.	12 mos.	term	> 6 mos.	1 year	Comment(s)
Methodological Quality Scoring						$\leq 6$ mos.			
DISC HERNIATI	ON AND RADI	CULITIS							
Manchikanti et al (3-5)	120 local	Local anesthetic or with Celestone	83% vs. 70%	82% vs. 73%	72% vs. 68%	Р	Р	Р	Positive large study.
RA, AC, F	anesthetic= 60	Number of							
11/12	Local anesthetic with steroids = 60	injections = $1$ to $4$							
Castagnera et al (6)	24	local anesthetic with steroid or	79.2%	79.2%	79.2%	Р	P = steroids	Р	A small study with positive
RA, AC, B		steroid plus morphine					N = local anesthetics		results
7/12		Number of injections=1							
Stav et al (7)	42	local anesthetic with steroid or	NA	NA	68% vs 11 8%	NA	NA	Р	A small study showing
RA, AC, B		IM steroid			(0.11.0)0				satisfactory
7/12		Number of injections=1 to 3							mprovement
Pasqualucci et al (8) RA, AC, B	40 of 160	Bupivacaine with methylpredniso lone acetate	NA	Single vs. continuous 58.5%, 73.7%	NA	NA	Р	NA	Small study with positive results
7/12				improvemen t					
DISCOGENIC PA	AIN	<u> </u>							
Manchikanti et al (11,12)	120	Local anesthetic or	68% vs. 77%	67% vs. 73%	72% vs. 68%	Р	Р	Р	Positive results
RA, AC, F		with Celestone							
10/12									
SPINAL STENOS	SIS								
Manchikanti et al (9)	60	Local anesthetic or with Celestone	77% vs. 87%	87% vs. 80%	73% vs. 70%	Р	Р	Р	Positive results
RA, AC, F		with constant							
10/12									
POST SURGERY	SYNDROME	Γ		Γ			Γ		
Manchikanti et al (10) RA, AC, F	56	Local anesthetic or with Celestone	68% vs. 68%	64% vs. 71%	71% vs. 64%	Р	Р	Р	Positive results

Participants	Interventions	Pain	Relief and Fur	Results				
		3 mos.	6 mos.	12 mos.	Short- term ≤ 6 mos.	Long-term		Commont(s)
						> 6 mos.	1 year	Comment(s)
	Participants	Participants Interventions	Participants Interventions 3 mos.	Participants       Interventions       Pain Relief and Funds         3 mos.       6 mos.	Participants       Interventions       Pain Relief and Function         3 mos.       6 mos.       12 mos.	ParticipantsInterventionsPain Relief and Function $3 \text{ mos.}$ $6 \text{ mos.}$ $12 \text{ mos.}$ Short-term $\leq 6 \text{ mos.}$	ParticipantsPain Relief and FunctionResultsInterventions3 mos.6 mos.12 mos.Short-term $\leq 6$ mos. $\leq 6$ mos. $\leq 6$ mos. $\leq 6$ mos. $\geq 6$ mos.	Participants     Pain Relief and Function     Results       Interventions $3 \text{ mos.}$ $6 \text{ mos.}$ $12 \text{ mos.}$ $56 \text{ mos.}$ $1 \text{ year}$ $6 \text{ mos.}$ $12 \text{ mos.}$ $1 \text{ year}$

RA = Randomized; AC = Active-Control; F = Fluoroscopy; B=Blind; P = positive; N = negative; NA = not applicable

Source: Diwan SA, Manchikant L, Benyamin RM, Bryce DA, Geffert S, Hameed H, Sharma ML, Abdi S, Falco FJE. Effectiveness of cervical epidural injections in the management of chronic neck and upper extremity pain. *Pain Physician* 2012; 15:E405-E434 (1).

Based on the present review of evidence, there is good evidence for disc herniation and fair evidence for axial or discogenic pain, central spinal stenosis, and post cervical surgery syndrome. Thus, cervical interlaminar epidural injections are indicated for these conditions with appropriate indications.

# COMPARISON OF EVIDENCE SYNTHESIS PUBLISHED BY BLUE CROSS BLUE SHIELD OF TENNESSEE

The policy quotes Hayes guidelines and states that policy is also similar to Milliman guidelines. However, as stated earlier, this is inappropriate as these guidelines are commercial, prepared with the purposes of providing recommendations to the industry with no peer review. They are expensive for a clinician to review them and they are not published on the NGC.

The cervical epidural policy information shows that,

"The current body of literature shows that CESIs are associated with some pain relief. However, the studies are variable in design. Well-designed studies that compare conservative management to CESI are needed. Well-designed studies that compare CESI with and without an anesthetic agent are needed. Trials are also needed that include longer follow-up in order to adequately examine the duration of any benefit associated with CESIs."

In contrast to this recommendation, there are multiple well-designed studies as shown above including a large number of patients for each condition studied. In fact, there are multiple studies for cervical disc herniation. The current policy has utilized outdated guidelines, even though the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine guidance was published in 2010. The evidence was only through 2009. Since then, there have been multiple manuscripts published. Even then, this guideline provides positive evidence for epidural injections. Armon, et al's reference was from 2007 and was limited to assessment of radicular lumbosacral pain as the title itself says.

The review by Benyamin is also old. It has been updated by Diwan, et al.

ASIPP guidelines utilized are from 2007 and 2009; however, these have been updated in 2013 as illustrated above.

North American Spine Society (NASS) guidelines were developed by surgeons, once again published in 2011 without inclusion of all up to date evidence.

In contrast to this, the above described evidence shows up-to-date literature with proper quality assessment and utilization of proper criteria in grading the strength of evidence.

# INDICATIONS, MEDICAL NECESSITY, TRAINING AND QUALIFICATIONS

It is essential to apply proper indications and medical necessity.

#### Common indications for cervical interlaminar epidurals are as follows:

- Chronic neck and/or upper extremity pain of at least 3 months duration which has failed to respond or poorly responded to non-interventional and non-surgical conservative management resulting from:
- Disc herniation/cervical radiculitis (evidence good)

- Cervical spinal stenosis (evidence fair)
- Post cervical surgery syndrome (evidence fair)
- Axial or discogenic pain without facet joint pathology or disc herniation (evidence fair)
- Intermittent or continuous pain causing functional disability.

#### Frequency:

- In the diagnostic phase, a patient may receive 2 procedures at intervals of no sooner than 2 weeks or preferably 4 weeks.
- In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency of interventional techniques should be 3 months or longer between each injection, provided that > 50% relief is obtained for  $2\frac{1}{2}$  to 3 months
- In the treatment or therapeutic phase, the epidural injections should be repeated only as necessary according to medical necessity criteria, and it is suggested that these be limited to a maximum of 4 times per year.

# **DOCUMENTATION REQUIREMENTS**

- 1. Complete initial evaluation including history and physical examination.
  - Physiological and functional assessment, as necessary and feasible.
  - Description of indications and medical necessity, as follows:
    - Suspected organic problem.
    - Pain and disability of moderate-to-severe degree.
  - No evidence of contraindications, such as severe spinal stenosis resulting in intraspinal obstruction, infection, or predominantly psychogenic pain.
  - Nonresponsiveness to conservative modalities of treatment.
  - Responsiveness to prior interventions with improvement in physical and functional status for repeat blocks or other interventions with appropriate consideration to the adverse effects including those of corticosteroids.

Patient safety and quality care mandate the healthcare professionals who perform any interventional techniques as defined by MedPAC are performed by appropriately trained providers who have:

- Successfully completed an accredited residency or fellowship program whose core curriculum includes the performance of interventional techniques, and/or
- Are diplomates of nationally recognized boards, such as those accredited by the American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA), subspecialty certification in pain medicine; the American Board of Pain Medicine (ABPM); or the American Board of Interventional Pain Physicians (ABIPP).

Exceptions for these requirements include a formal residency or fellowship program with curriculum including interventional techniques, with documentation of such curriculum and training requirements.

At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics as well as proficiency in diagnosis and management of disease, the technical performance of the procedure and utilization of the required associated imaging modalities.

An exception is also provided to all physicians who have been performing these procedures for at least 10 years on a regular basis with credentials approved by either a CMS-accredited hospital or a surgery center.

#### IMAGING:

The use of imaging guidance, particularly fluoroscopy or computed tomography, with the use of injectable radiopaque contrast material has been shown to enhance the accuracy and safety of needle placement for all epidural injection procedures, including cervical interlaminar epidural injections. Consequently, imaging guidance must be mandated except when it is contraindicated.

## **CONCLUSION:**

In conclusion, we appreciate the efforts to establish standards. However, the process utilized does not appear to be scientific. Based on this, we would recommend that the policy be reversed and cervical epidural injections be covered for disc herniation, axial neck or discogenic pain without facet joint pain, spinal stenosis, and post surgery syndrome. However, it is essential to establish appropriate indications and medical necessity. The policy must also include appropriate training and settings for these procedures to be performed.

Once again, thank you for the opportunity to provide these comments. If you have any further questions, please feel free to contact us.

Sincerely,

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