American Society of Interventional Pain Physicians

"The Voice of Interventional Pain Management"

81 Lakeview Drive, Paducah, KY 42001
Tel.: (270) 554-9412; Fax : (270) 554-8987
E-mail:asipp@asipp.org

February 3, 2012

Bruce Bodaken
Chairman, President and Chief Executive Officer
Blue Shield of California
Corporate Headquarters
50 Beale Street
San Francisco, CA 94105-1808

RE: Medical Policy Epidural Steroid Injections

Mr. Bodaken,

On behalf of the American Society of Interventional Pain Physicians (ASIPP) and California Society of Interventional Pain Physicians (CASIPP), we would like to thank you for publishing the medical policy on epidural steroid injections. However, this policy has elicited significant debate and at times controversy among physicians. Consequently, the primary objective of our comments is to ensure that these procedures are provided appropriately and that patients insured by Blue Shield of California, and even the entire country, which may follow soon, maintain access to care. We are hopeful that you will take our comments into consideration and re-evaluate the evidence.

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 7,000 appropriately trained and qualified physicians practicing interventional pain management in the United States.

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 (1).

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 discectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent, or intractable pain (2).

We will outline the concerns related to Blue Shield of California's policy on epidural steroid injections as follows:

We request that appropriate evaluations be performed either by yourself or the agency you have hired based on the principles of the Institute of Medicine (IOM) about clinical guidelines.

As you are well aware, the IOM defined clinical guidelines as, "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (3). Consequently, all professionals consider clinical guidelines as constructive responses to the reality that practicing physicians require assistance for assimilating and applying the exponentially expanding, often contradictory, body of medical knowledge (4). However, it also has been stated that clinical guidelines should not attempt to supplant the independent judgment of a clinician in responding to particular clinical situations, but rather the guidelines attempt to define practices that meet the needs of most patients under most circumstances (5). Essentially, it is the objective of guidelines to enable the implementation of evidence-based medicine and comparative effectiveness research in medical decision-making with the goal of encouraging effective care (6-15). Consequently, it is expected that the **specific clinical recommendations that are contained within practice guidelines have been systematically developed by panels of experts who have access to all available evidence, have an understanding of the clinical problem, and have clinical experience with the procedure being assessed, as well as relevant research methods in order to make considered judgments**. Above all, these panels are expected to be objective and to produce recommendations that are not only up to date, but also are unbiased and free from all conflicts of interest.

Sniderman and Furberg (4) described the conflicts, controversies, and limitations of the guideline process. Further, the integrity of the guideline or systematic review preparation must be maintained (16,17). The components of integrity include transparency, accountability, consistency, and independence. These factors have been shown to be lacking in many guidelines (10-14,18,19) as well as ACOEM guidelines (20-22). There are numerous issues related to not only the above guidelines, but also the guidelines published by the Official Disability Guidelines, or ODG (23). These guidelines showed multitudes of conflicts of interest and different conclusions based on specific interests and the advancement of agendas, and different conclusions by the same authors based on individual guidelines. In contrast, the guidelines by the American Society of Interventional Pain Physicians incorporate a much more comprehensive policy and have extensively reviewed numerous interventions (6,24-49).

A formal set of rules must complement medical training and common sense for clinicians so they may interpret the results of clinical research effectively (6-11,50,51). However, knowing the tools of evidence-based practice is necessary, but not completely sufficient for delivering the highest quality patient care. Clinical guidelines must incorporate not only the work of methodologists, but also clinicians who actually practice medicine and are experts in the technique being reviewed. In fact, Congress has been concerned about the issue of appropriate representation by clinical specialists versus methodologists or physicians without expertise in a particular intervention. Basically, what we are requesting is that guideline preparers follow the rules they have established, rather than changing the rules when evidence is in favor of an intervention or is found to be opposite of their preformed conclusion(s). In fact, IOM has extensively published methodology for systematic reviews and guideline preparation. Further, the entire concept of comparative effectiveness research and PCORI are also based on appropriate evaluations (7-11,16,52-54).

Methodologists also have a problem understanding the design of a study because of their single focus on placebo control and efficacy and their interest only in the difference between placebo and treatment groups. However, this ignores numerous factors with regards to the mechanism of action of local anesthetics and steroids, the effect of an injection of inactive substances into active structures – so-called placebo with an inappropriate design, and the differences between an active-control and placebo control. The literature is replete with inappropriate placebo designs in interventional pain management, illustrating the effectiveness of inactive substances when injected into active structures, inaccurate assumptions of local anesthetic as a placebo, showing equal effectiveness as steroids in numerous studies, and finally, a lack of consideration of the numerous effects related to placebo and nocebo (55-82). However, the only one appropriately performed placebo-controlled study (83) has illustrated no effect of sodium chloride

solution when injected into an inactive structure rather than into closed spaces over the nerve roots and other active structures.

It is essential to provide proper evaluation of the evidence, not to reach inappropriate conclusions by selective elimination or disqualification of evidence. The evidence synthesis by Triad Health Care, Inc., shows that they have inadvertently or purposefully eliminated much of the literature which is positive and included only all the negative literature.

With regards to the specifics about the medical policy for epidural steroid injections:

1. We agree with the definition of medical necessity, investigational and experimental, and split evaluation.

2. We appreciate the inclusion of epidural steroid injections without use of fluoroscopic guidance and that the injection of a contrast medium may be considered not medically necessary. This is a long awaited yet bold statement – a long advocated ASIPP position.

3. In reference to diagnostic epidural steroid injections or selective nerve root block, the indications are appropriate; however, the only issue relates to if the first injection is performed under fluoroscopy and contrast medium is used for guidance, a second block is not indicated unless there is evidence of multilevel pathology. Transforaminal epidurals must always be performed under fluoroscopy utilizing contrast medium.

4. In reference to therapeutic epidural steroid injections (transforaminal, translaminar, or caudal), translaminar may not be the appropriate language. It should state "interlaminar" rather than "translaminar." The statement in the first paragraph is appropriate.

5. With regards to the statement in the second paragraph under this section, there is no provision anywhere in the literature or CPT coding to perform interlaminar epidurals at more than one level. However, there should be a provision to perform these for different regions with 2 interlaminar epidurals such as cervical and thoracic as one region, and lumbar and sacral as the second region. All Medicare regulations follow this and most of the private insurers; ASIPP guidelines specifically illustrate these points (24,84,85).

6. The third paragraph once again comes to the same point. If a patient receives facet joint blocks or sacroiliac joint blocks and they are shown to be negative for this purpose, we do not believe it is essential to send the patient back home and have the patient return for a second visit. This only increases the number of procedures performed. Instead, the statement should be that all procedures must be performed on the same day in one session; however, only one type of procedure(s), such as either facet joint blocks or sacroiliac joint blocks or epidurals, will be considered medically necessary and be reimbursed. Thus, this will improve convenience to the patient, physician, facility, and all concerned and also reduce excessive costs to Blue Shield.

   In addition, this paragraph has a statement stating that lumbar and cervical blocks should not be performed on the same date of service. This is not appropriate. This will only increase cost to you and overall inconvenience to the patient. However, this may actually benefit providers except for significant inconvenience. Thus, in line with multiple regulations already in existence by Medicare, Medicaid, and other insurers, it should be region specific, and you should encourage physicians to perform all procedures on the same day as long as it is safe.

7. The next paragraph is based on the limited long-term benefit of performing epidural steroid injections as an isolated intervention. To some extent we agree; however, there is no evidence thus far that rehabilitative care via therapeutic exercise is mandatory, necessary, or even useful. Injections performed in isolation on a long-term basis, in conjunction with continued activity and an exercise program, can provide long-term relief. As you know, these injections are expected to provide only on average 12 to 16 weeks of relief with each one after the first 2 in the diagnostic phase (68-79). Thus, this statement needs to be removed or modified. We will illustrate the evidence for both interlaminar epidural injections, as well as transforaminal epidural injections below.

8. The use of epidural injections being medically necessary for only severe spinal stenosis may not be very appropriate. Patients with severe spinal stenosis may not be candidates for epidural injections. Further, they may not even respond. The indications should be mild and moderate symptomatic stenosis and severe stenosis not meeting the criteria for surgery or the patient not willing to undergo surgical interventions.

9. The limit on caudal epidural injections up to only L5/S1 and the rationale that it does not reach above L5/S1 has no scientific basis. This also indirectly encourages transforaminal epidural injections; however, these should not be encouraged considering the significant risk, specifically in postfusion patients or postsurgery patients on the left side. However, they should be performed only when they are appropriately indicated. Caudal epidural injections are the best option for all types of postsurgery patients including postfusion. However, caudal epidurals routinely reach above S1 based on the volume. If one uses a volume of 1 or 2 mL, the review is accurate in that aspect. Otherwise, unless there is obstruction, in which case caudal is the best choice with postsurgery syndrome, caudal reaches above L4/5. This review may be accurate in that if the lesion exists at L3/4 or above, it may not be indicated.

10. We agree with repeat epidural steroid injections after a trial of 2 injections if there is a lack of improvement.

11. The next one relates to no more than 3 epidural steroid injections should be performed per episode of pain. Once again, we are getting into the same philosophy of 3 epidural injections which has been denounced by almost all authorities because it lacks any scientific basis. Essentially, no more than 2 epidural steroid injections are required unless the patient shows significant improvement. However, after this, if the patient does show significant improvement, you enter into the therapeutic phase and 4 injections per region per year after this initial treatment would be extremely appropriate. Thus, the language needs to be altered.

12. Your next statement says there is no scientific evidence to support the scheduling of a series of 3 injections. However, in the above paragraph, you just recommended those. We agree that the medical necessity of subsequent injections should be evaluated individually and based on the response of at least 2 months in the therapeutic phase.

13. Finally, prior to evidence demonstration, we would like to point out that the policy does not really cover long-term, repeated, or therapeutic epidural injections or selective nerve root blocks for any indication because it is considered not medically necessary. Further, your evidence synthesis and guidelines also do not cover injections for axial or discogenic pain specifically after ruling out facet joint pain and sacroiliac joint pain as there is no other cause for this pain and it needs to be managed as well as low back pain secondary to postsurgery syndrome. Thus, evidence is contrary to the policy as illustrated below. Further, again as stated earlier, indications should be defined separately as the evidence is variable for disc herniation and radiculitis, axial or discogenic pain,

postsurgery syndrome, spinal stenosis, and technique – caudal, interlaminar, transforaminal, and per region cervical and thoracic as a separate region from lumbar and sacral.

The ASIPP guidelines and multiple systematic reviews (18,24-49,86-88) of caudal epidural injections, lumbar interlaminar epidural injections, lumbar transforaminal epidural injections, and cervical interlaminar epidural injections showed variable evidence based on each condition.

1.0 CAUDAL EPIDURAL INJECTIONS

Conn et al (35) in a systematic review evaluating the effect of caudal epidural injections with or without steroids in managing various types of chronic low back and lower extremity pain emanating as a result of disc herniation or radiculitis, postlumbar surgery syndrome, spinal stenosis, and chronic discogenic pain without disc herniation or radiculitis has shown Level I evidence for short- and long-term relief of chronic pain secondary to disc herniation or radiculitis and discogenic pain without disc herniation or radiculitis. Further, this systematic review also provided an indicated level of evidence of II-1 or II-2 for caudal epidural injections in managing chronic pain of postlumbar surgery syndrome and spinal stenosis. The results of this systematic review were provided utilizing contemporary systematic review methodology utilizing randomized trials and observational studies, even though most of the evidence was derived from randomized trials.

Table 1 illustrates the studies utilized in managing lumbar disc herniation or radiculitis with caudal epidural injection (89-93). Another manuscript was published (94) which was not included in this analysis. The only study included in Conn et al's (35) analysis by Manchikanti et al (95) was performed with fluoroscopic visualization. As illustrated in the updated table, which also includes the newer studies or excluded studies from Conn et al (35), show positive results, specifically when they were performed under fluoroscopy (89,95-99), whereas all the negative studies were performed without fluoroscopy, including the most recent one by Iversen et al (100), which was performed and had a multitude of flaws in their inclusion criteria and analysis, along with imaging.

Table 1. *Results of randomized trials of the effectiveness of caudal epidural steroid injections in managing pain of lumbar disc herniation/radiculitis.*

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2011 (69,95)	RA, DB, F	120	77% vs. 80%	77% vs 82%	70% to 77%	*P*	*P*
Dashfield et al 2005 (89)	RA, DB, F	Caudal = 30 Endoscopy = 30	SI	SI	NA	*P*	NA
Bush and Hillier 1991 (90)	RA, DB, B	23	SI	NSI	NSI	*P*	N
Mathews et al 1987 (91)	RA, DB	C = 34 T = 23	SI	SI	SI	N	*P*
Hesla and Breivik 1979 (92)	RA, DB	69 patients: crossover design	77% vs 29%	59% vs 25%	59% vs 25%	*P*	*P*
Breivik et al 1976 (93)	RA, DB, B	C = 19 T = 16	20% vs 50%	20% vs 50%	NA	*P*	NA
Iversen et al (100)	R, PC, B	116	N	N	N	U	U
Ackerman & Ahmad (96)	R, AC, F	90	Caudal = 17 of 30 (57%) Interlaminar=18 of 30 (60%) Transforaminal= 25 of 30 (83%)	Caudal = 17 of 30 (57%) Interlaminar=18 of 30 (60%) Transforaminal= 25 of 30 (83%)	NA	P	NA
McCahon et al (97)	R, AC, B	33	SI in 40 mg group	NA	NA	P	NA
Makki et al (98)	R, AC, F	57	SI in lateral group	NA	NA	P	NA

RA = Randomized; DB = Double-Blind; AC = Active-Control; PC = Placebo Control; F = Fluoroscopy; B = Blind; NA = Not Available; SI = Significant Improvement; NSI = No Significant Improvement; vs = Versus; *P* = Positive; N = Negative; U = Unclear

Adapted and modified from Conn A et al. Systematic review of caudal epidural injections in the management of chronic low back pain. Pain Physician 2009; 12:109-135 (35).

Conn et al (35) showed the evidence of randomized trials in managing low back pain from postlumbar surgery syndrome as illustrated in Table 2 with a demonstrated evidence of Level II-1 or II-2. Only one study was performed under fluoroscopy (70). Table 3 shows the evidence in spinal stenosis was also

similar to postlumbar surgery syndrome with Level II-1 or Level II-2, with only one study being performed under fluoroscopy (71). Table 4 illustrates the results of studies of the effectiveness of caudal epidural injections in managing discogenic pain; however, the evidence in this category was shown to be Level I.

Table 2. *Results of randomized trials in managing low back pain of postsurgery syndrome with caudal epidural injections.*

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2010, (70,101)	RA, DB, F	40	65% to. 70%	60%	60% to 65%	P	P
Revel et al 1996 (102)	RA, B	Forceful injection = 29 Regular = 31	NA	49% vs 19%	NA	P	P
Hesla and Breivik 1979 (92)	RA, DB, B	69 patients: crossover design	77% vs 29%	59% vs 25%	59% vs 25%	P	P

RA = Randomized; DB = Double-Blind; B = blind; F = Fluoroscopy; NA = Not Available; vs = Versus; P = Positive; N = Negative

Adapted and modified from Conn A et al. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009; 12:109-135 (35).

Table 3. *Results of the effectiveness of managing spinal stenosis with caudal epidural injections.*

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2011 (71,103)	RA, DB, F	40	50% to 65%	60% to 65%	55% to 65%	P	P
Ciocon et al 1994 (104)	O, B	30	SI	SI	NA	P	NA
Botwin et al 2007 (105)	O, F	34	65%	62%	54%	P	P

RA = randomized; DB = Double-Blind; F = Fluoroscopy; B = Blind; O = Observational; NA = Not Available; SI = Significant Improvement; vs. = Versus; P = Positive; N = Negative

Adapted and modified from Conn A et al. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009; 12:109-135 (35).

Table 4. *Results of randomized and observational studies of the effectiveness of caudal epidural steroid injections in managing discogenic pain.*

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2011 (68)	RA, DB, F	64	78%	75% to 81%	72%	P	P
Manchikanti et al 2001 (106)	O, F	70	95%	85%	61% to 73%	P	P
Manchikanti et al 2002 (107)	O, F	62	86%	60%	NA	P	NA

*Indicates use of fluoroscopy

RA = Randomized; DB = Double-Blind; O = Observational; ; F = Fluoroscopy; NA = Not Available; P = Positive; N = Negative

Adapted and modified from Conn A et al. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009; 12:109-135 (35).

2.0 INTERLAMINAR EPIDURAL INJECTIONS

As shown repeatedly, multiple systematic reviews have provided negative opinions for lumbar interlaminar epidural injections. However, 2 systematic reviews have evaluated lumbar and cervical interlaminar epidurals (36,37). They arrived at conflicting conclusions with the systematic review of the effectiveness of cervical epidurals in the management of chronic neck pain illustrating Level II-1 evidence in managing chronic neck and upper extremity pain (3); whereas, the evidence is Level II-2 for the short-term relief of pain from disc herniation or radiculitis utilizing blind interlaminar epidural steroid injections and lack of evidence for long-term relief. However, all lumbar interlaminar and cervical interlaminar studies were performed without fluoroscopy. There are studies with fluoroscopy which change the results (72,73). The evidence for blind lumbar interlaminar epidurals in disc herniation and radiculitis is negative (36). Thus, these should be mandated to be performed under fluoroscopy and we believe that the results will be similar to caudal and transforaminal when performed appropriately. We do not recommend lumbar interlaminar epidural injections in postsurgery syndrome unless the needle placement and epidural entry can be performed below the level of the scar to avoid complications. Thus, as shown in Table 5, published randomized trials of the effectiveness of lumbar interlaminar epidural steroid injections performed under fluoroscopy with an active-control design, which are all judged to be high quality studies, showed positive results for disc herniation, axial or discogenic pain without facet or sacroiliac joint pain or radiculitis, and spinal stenosis. These results are very similar to transforaminal and caudal epidural injections.

Table 5. *Results of randomized and observational studies of the effectiveness of fluoroscopic lumbar interlaminar epidural steroid injections in managing disc herniation, axial or discogenic pain, and spinal stenosis.*

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2010 (72)	RA, C, F	Group I - no steroid=35 Group II - steroid=35	83% vs. 86%	63% vs. 89%	74% vs. 86%	P	P
Manchikanti et al 2010 (73)	RA, C, F	Group I - no steroid=35 Group II - steroid=35	77% vs. 86%	80% vs. 86%	80% vs. 80%	P	P
Manchikanti et al 2011 (108)	RA, C, F	Group I - no steroid=30 Group II - steroid=30	77% vs. 77%	73% vs. 73%	70% vs. 63%	P	P
Candido et al 2008 (109)	R, AC, F	Total=60 TF=30 PIL=30	VAS scores with no significant difference between the groups 42.93 versus 46.6	Improvement in VAS scores from baseline but no differences between the groups	NA	P	P
Ackerman & Ahmad 2007 (96)	R, AC, F	Total=90 Caudal = 30 Interlaminar = 30 Transforaminal = 30	Caudal = 17 of 30 (57%) Interlaminar=18 of 30 (60%) Transforaminal=25 of 30 (83%)	Caudal = 17 of 30 (57%) Interlaminar=18 of 30 (60%) Transforaminal= 25 of 30 (83%)	NA	P	P
Lee et al 2009 (110)	R, AC, F	Total=93 IL=34 TF=59	Roland Pain Score Transforaminal = 3.34 to 1.59 Interlaminar = 3.25 to 1.57	NA	NA	P	NA
Rados et al 2011 (111)	R, AC, F	Total=64 IL=32 TF=32	TF=53% IL=75%	TF=53% IL=75%	NA	P	P

*Indicates use of fluoroscopy

RA = Randomized; AC = Active-control; F = Fluoroscopy; DB = Double-Blind; TF = transforaminal; IL= Interlaminar; PIL = Parasagittal Interlaminar; NA = Not Available; P = Positive; N = Negative

The systematic review of cervical epidural injections (37) also utilized blind cervical epidural studies with significant evidence as shown in Table 6. However, none of the studies were performed under fluoroscopy at that time.

In fact, more recent studies, which are now incorporated into Table 6, showed positive results for disc herniation, axial neck pain without disc herniation, radiculitis, or facet joint pain, spinal stenosis, and cervical postsurgery syndrome.

Table 6. *Results of randomized trials of fluoroscopic cervical interlaminar epidural injections in managing disc herniation, axial or discogenic pain, spinal stenosis, and cervical postsurgery syndrome.*

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 months	Long-term relief > 6 months
Manchikanti et al 2010 (112)	RA, C, F	Group I - no steroid=35 Group II - steroid=35	77% vs. 86%	80% vs. 86%	80%	P	P
Manchikanti et al 2010 (76)	RA, C, F	Group I - no steroid=35 Group II - steroid=35	89% vs. 83%	77% vs. 74%	77% vs. 77%	P	P
Manchikanti et al 2012 (77)	RA, C, F	Group I - no steroid=30 Group II - steroid=30	77% vs. 87%	87% vs. 80%	73% vs. 70%	P	P
Manchikanti et al 2012 (78)	RA, C, F	Group I - no steroid=28 Group II - steroid=28	68% vs. 68%	64% vs. 71%	71% vs. 64%	P	P
Castagnera et al 1994 (113)	RA	Local anesthetic with steroids =14 Local anesthetic with steroids and morphine =10	79%	79%	79%	P	P
Stav et al 1993 (114)	RA	C = 17 T = 25	12% vs 68%	12% vs 68%	12% vs 68%	P	P
Pasqualucci et al 2007 (64)	RA	Single = 20 Continuous = 20 Over 180 days	NA	58% vs 74%	NA	P	NA

RA = randomized; C = control; F = Fluoroscopy; T = treatment; vs = versus; P = positive; N = negative; NA = not available

Modified and updated from Benyamin RM et al. Systematic review of the effectiveness of cervical epidurals in the management of chronic neck pain. *Pain Physician* 2009; 12:137-157 (37).

3.0 LUMBAR TRANSFORAMINAL EPIDURAL INJECTIONS

The systematic review by Buenaventura et al (38) indicated the evidence is Level II-1 for short-term relief and Level II-2 for long-term relief in managing chronic low back and lower extremity pain. Table 7 illustrates randomized trials of the effectiveness of lumbar transforaminal epidural injections.

Table 7. *Results of randomized trials of the effectiveness of lumbar transforaminal epidural injections.*

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Karppinen et al 2001 (58)	RA, DB	C = 80 T = 80	SICH	NSI	NSI	P	N
Riew et al 2000/ 2006 (115,116)	P, RA, DB	55	NA	NA	33% vs. 71% (avoided surgery)	P	P
Jeong et al 2007 (117)	RA, DB	239	PG 99 of 112 G 90 of 127	PG 64 of 106 G 78 of 116	NA	P	NA
Vad et al 2002 (118)	RA	48	NA	NA	48% vs. 84%	P	P
Ghahreman et al 2010 (83)	RA, PC	150	Intramuscular saline=13% Intramuscular steroids=21% Transforaminal saline=19% Transforaminal local anesthetic=7% Transforaminal epidural=54%	NA	NA	P	NA
Ng et al 2005 (119)	RA, AC	49	Pain Bupivacaine=47.5% Bupivacaine + steroid=41.5% ODI Bupivacaine=45% Bupivacaine + steroid=35%	NA	NA	P	NA
Lee et al 2009 (110)	RA, AC	93	Roland Pain Score Transforaminal = 3.34 to 1.59 Interlaminar = 3.25 to 1.57	NA	NA	P	NA
Ackerman & Ahmad 2007 (96)	RA, AC	90	Caudal = 17 of 30 (57%) Interlaminar=18 of 30 (60%) Transforaminal=25 of 30 (83%)	Caudal = 17 of 30 (57%) Interlaminar=18 of 30 (60%) Transforam	NA	P	NA

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
				inal=25 of 30 (83%)			
Candido et al 2008 (109)	RA, AC	60	VAS scores with no significant difference between the groups 42.93 versus 46.6	Improvement in VAS scores from baseline but no differences between the groups	NA	P	NA
Park et al 2010 (120)	RA, AC	106	The reduction of pain in the dexamethasone group was 40% and in triamcinolone group was 71%. Proportion of patients with relief were not described.	NA	NA	P	NA
Rados et al 2011 (111)	RA, AC	64	TF=53% IL=75%	TF=53% IL=75%	NA	P	NA
Tafazal et al 2009 (121)	RA, AC	76	VAS change Bupivacaine = 24.3 Bupivacaine + steroid = 27.4 ODI change Bupivacaine = 13.8 Bupivacaine + steroid = 13.6	P	NA	P	P

RA = randomized; DB = double blind; P = prospective; C = control; T = treatment; PG = pre-ganglionic; G = ganglionic; SICH = significant improvement in contained disc herniation; NSI = no significant improvement; vs. = versus; NA = not available; P = positive; N = negative.

Adapted from Buenaventura RM et al. Systematic review of therapeutic lumbar transforaminal epidural steroid injections. *Pain Physician* 2009; 12:233-251 (38).

4.0 INDICATIONS AND MEDICAL NECESSITY

All in all, epidural injections must be recommended with 2 procedures in the diagnostic phase and 4 therapeutic interventions per region per year after the diagnostic phase is completed, if indications and medical necessity as described above are documented.

- Common indications for caudal epidural injections are as follows:
  - Chronic low back and/or lower extremity pain which has failed to respond or poorly responded to noninterventional and nonsurgical conservative management resulting from:

- Disc herniation/lumbar radiculitis
- Lumbar spinal stenosis
- Lumbar postsurgery syndrome
- Epidural fibrosis
- Degenerative disc disease/discogenic low back pain
- Absence of facet joint pain determined by controlled local anesthetic blocks
- Intermittent or continuous pain causing functional disability
- Average pain level of ≥ 6 on a scale of 0 to 10.

♦ Indications for lumbar interlaminar injections are the same as for caudal epidural injections, except for postsurgery syndrome.
- Caudal epidural is the modality of choice for postsurgery syndrome.

♦ Common indications for cervical interlaminar injections are as follows:
- Chronic neck and/or upper extremity pain which has failed to respond or poorly responded to noninterventional and nonsurgical conservative management resulting from:
- A herniated, protruded, or extruded disc with or without radiculitis
- Cervical spinal stenosis
- Cervical postsurgery syndrome
- Degenerative disc disease
- Absence of facet joint pain determined by controlled local anesthetic blocks
- Intermittent or continuous pain causing functional disability
- Average pain level of ≥ 6 on a scale of 0 to 10.

♦ Common indications for thoracic interlaminar injections are as follows:
- Chronic mid back or upper back pain which has failed to respond or poorly responded to noninterventional and nonsurgical conservative management resulting from:
- A herniated, protruded, or extruded disc with or without radiculitis
- Thoracic spinal stenosis
- Thoracic postsurgery syndrome
- Degenerative disc disease
- Absence of facet joint pain determined by controlled local anesthetic blocks
- Intermittent or continuous pain causing functional disability
- Average pain level of ≥ 6 on a scale of 0 to 10.

♦ Common indications for lumbar transforaminal epidurals are provided for diagnostic and therapeutic purposes.

Diagnostic Indications

- To identify an inflamed nerve root in a patient with a history of radicular pain when results of visual anatomic studies and neurophysiologic studies are not collaborative.
- To identify the pain generator when patients have multiple abnormalities on visual anatomic studies.
- To determine the symptomatic level in multilevel disc herniation.
- To determine a primary pain generator in the spine-hip syndrome.

- To determine a previously undocumented nerve root irritation as a result of spondylolisthesis.
- To determine the symptomatic level in multilevel stenosis.
- To determine the symptomatic root in patients with documented postoperative fibrosis.

Therapeutic Indications

- Average pain levels of ≥ 6 on a scale of 0 to 10.
- Intermittent or continuous pain causing functional disability.
- Chronic low back and/or lower extremity pain which has failed to respond or poorly responded to noninterventional and nonsurgical conservative management.
- Chronic low back and/or lower extremity pain resulting from:
- Disc herniation/radiculitis
- Failed back surgery syndrome without extensive scar tissue and hardware
- Spinal stenosis with radiculitis
- Discogenic pain with radiculitis.

5.0 FREQUENCY OF INTERVENTIONS

- ♦ Guidelines for the frequency of interventions apply to epidural injections caudal, interlaminar, and transforaminal.
- ♦ In the diagnostic phase, a patient may receive 2 procedures at intervals of no sooner than one week or preferably 2 weeks.
- ♦ In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency of interventional techniques should be 2 months or longer between each injection, provided that >50% relief is obtained for 2 months.
- ♦ If the neural blockade is applied for different regions, they may be performed at intervals of no sooner than one week and preferably 2 weeks for most types of procedures. The therapeutic frequency may remain at intervals of at least 2 months for each region. It is further suggested that all regions be treated at the same time, provided all procedures can be performed safely.
- ♦ 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.
- ♦ Cervical and thoracic regions are considered as one region and lumbar and sacral are considered as one region.

In summary, there is significant evidence now with repeat injections appropriately performed under fluoroscopy for all types of epidural injections.

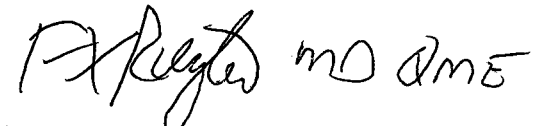
SUMMARY

While we applaud and also request that appropriate guidelines be utilized, the guidelines should never be either prescriptive or proscriptive; they should be patient-oriented and evidence-based. There is substantial bias in multiple guidelines, along with yours.

Once again we would like to thank you for this opportunity to present our views. If you have any further questions, please feel free to contact us.

Laxmaiah Manchikanti, MD
Chairman of the Board and Chief Executive Officer, ASIPP and SIPMS
Medical Director, Pain Management Center of Paducah
Associate Clinical Professor, Anesthesiology and Perioperative Medicine
University of Louisville, Kentucky
2831 Lone Oak Road
Paducah, KY 42003
270-554-8373 ext. 101
drm@asipp.org

Standiford Helm, MD
President, ASIPP
Medical Director, Pacific Coast Pain Management Center
24902 Moulton Parkway, Suite 200
Laguna Hills CA 92637
949-462-0560
drhelm@pcpmc.com



Francis Riegler, MD
President, CASIPP
Universal Pain Management
819 Auto Center Drive, Suite A
Palmdale, CA 93551
friegler@upmgt.com

Lee Snook, MD
AMA Delegate for ASIPP
Metropolitan Pain Management Consultants, Inc.
2288 Auburn Blvd, Suite 106
Sacramento CA 95821
lsnook@pain-mpmc.com

REFERENCES

1. The National Uniform Claims Committee. Specialty Designation for Interventional Pain Management- 09. http://www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf
2. Medicare Payment Advisory Commission. 2001. Report to the Congress: Paying for interventional pain services in ambulatory settings. Washington, DC: MedPAC. December. 2001. http://www.medpac.gov/publications/congressional_reports/dec2001PainManagement.pdf
3. Field MJ, Lohr KN (eds). Committee to Advise the Public Health Service on Clinical Practice Guidelines, Institute of Medicine. *Clinical Practice Guidelines*. *Directions for a New Program*. National Academy Press, Washington, 1990.
4. Sniderman AD, Furberg CD. Why guideline-making requires reform. *JAMA* 2009; 301:429-431.
5. Eden J, Wheatley B, McNeil B, Sox H (eds). Developing trusted clinical practice guidelines. In: *Knowing What Works in Health Care: A Roadmap for the Nation*. National Academies Press, Washington, DC, 2008, pp 121-152.
6. Manchikanti L, Singh V, Helm S, Schultz DM, Datta S, Hirsch J. An introduction to an evidence-based approach to interventional techniques in the management of chronic spinal pain. *Pain Physician* 2009; 12:E1-E33.
7. Manchikanti L, Falco FJE, Boswell MV, Hirsch JA. Facts, fallacies, and politics of comparative effectiveness research: Part 1. Basic considerations. *Pain Physician* 2010; 13:E23-E54.
8. Manchikanti L, Falco FJE, Boswell MV, Hirsch JA. Facts, fallacies, and politics of comparative effectiveness research: Part 2. Implications for interventional pain management. *Pain Physician* 2010; 13:E55-E79.
9. Eden J, Wheatley B, McNeil B, Sox H. *Knowing What Works in Health Care: A Roadmap for the Nation*. National Academies Press, Washington, DC, 2008.
10. Manchikanti L, Datta S, Derby R, Wolfer LR, Benyamin RM, Hirsch JA. A critical review of the American Pain Society clinical practice guidelines for interventional techniques: Part 1. Diagnostic interventions. *Pain Physician 2010; 13:E141-E174.*
11. Manchikanti L, Datta S, Gupta S, Munglani R, Bryce DA, Ward SP, Benyamin RM, Sharma ML, Helm II S, Fellows B, Hirsch JA. A critical review of the American Pain Society clinical practice guidelines for interventional techniques: Part 2. Therapeutic interventions. *Pain Physician* 2010; 13:E215-E264.
12. Chou R. Critiquing the critiques: The American Pain Society guideline and the American Society of Interventional Pain Physicians' response to it. *Pain Physician* 2011; 14:E69-E73; Response: Manchikanti L, Gupta S, Benyamin R, Munglani R, Datta S, Hirsch JA, Ward SP. In response from Manchikanti et al. *Pain Physician* 2011; 14:E73-E80.
13. Letter to Robin Hashimoto, Washington State Health Care Authority, from American Society of Interventional Pain Physicians RE: Health Technology Assessment for Spinal Injections, November 24, 2010.
14. Manchikanti L, Benyamin RM, Falco FJE, Caraway DL, Datta S, Hirsch JA. Guidelines warfare over interventional techniques: Is there a lack of discourse or straw man? *Pain Physician* 2012; 15:E1-E26.
15. Chou R, Atlas SJ, Loeser JD, Rosenquist RW, Stanos SP. Guideline warfare over interventional therapies for low back pain: Can we raise the level of discourse? *J Pain* 2011; 12:833-839.
16. Guirguis-Blake J, Calonge N, Miller T, Siu A, Teutsch S, Whitlock E; U.S. Preventive Services Task Force. Current processes of the U.S. Preventive Services Task Force: Refining evidence-based recommendation development. *Ann Intern Med* 2007; 147:117-122.
17. Petitti DB, Teutsch SM, Barton MB, Sawaya GF, Ockene JK, DeWitt T; U.S. Preventive Services Task Force. Update on the methods of the U.S. Preventive Services Task Force: Insufficient evidence. *Ann Intern Med* 2009; 150:199-205.

18. Chou R, Huffman L. *Guideline for the Evaluation and Management of Low Back Pain: Evidence Review*. American Pain Society; Glenview, IL, 2009.
19. Chou R, Huffman L. *Use of Chronic Opioid Therapy in Chronic Noncancer Pain: Evidence Review*. American Pain Society; Glenview, IL: 2009. www.ampainsoc.org/pub/pdf/Opioid_Final_Evidence_Report.pdf
20. American College of Occupational and Environmental Medicine (ACOEM) Low back Disorders. In *Occupational Medicine Practice Guidelines: Evaluation and Management of Common Health Problems and Functional Recovery of Workers*, Second Edition. American College of Occupational and Environmental Medicine Press, Elk Grove Village, 2007.
21. American College of Occupational and Environmental Medicine (ACOEM) Chronic Pain. In *Occupational Medicine Practice Guidelines: Evaluation and Management of Common Health Problems and Functional Recovery of Workers*, Second Edition. American College of Occupational and Environmental Medicine Press, Elk Grove Village, 2008.
22. Manchikanti L, Singh V, Derby R, Schultz DM, Benyamin RM, Prager JP, Hirsch JA. Reassessment of evidence synthesis of occupational medicine practice guidelines for interventional pain management. *Pain Physician* 2008; 11:393-482.
23. Dennison PL, Kennedy CW. *Official Disability Guidelines*, 15th ed. Work Loss Data Institute, Encinitas, 2010.
24. Manchikanti L, Boswell MV, Singh V, Benyamin RM, Fellows B, Abdi S, Buenaventura RM, Conn A, Datta S, Derby R, Falco FJE, Erhart S, Diwan S, Hayek SM, Helm S, Parr AT, Schultz DM, Smith HS, Wolfer LR, Hirsch JA. Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain. *Pain Physician* 2009; 12:699-802.
25. Manchikanti L, Boswell MV, Singh V, Derby R, Fellows B, Falco FJE, Datta S, Smith HS, Hirsch JA. Comprehensive review of neurophysiologic basis and diagnostic interventions in managing chronic spinal pain. *Pain Physician* 2009; 12:E71-E120.
26. Manchikanti L, Boswell MV, Datta S, Fellows B, Abdi S, Singh V, Benyamin RM, Falco FJE, Helm S, Hayek S, Smith HS. Comprehensive review of therapeutic interventions in managing chronic spinal pain. *Pain Physician* 2009: 12:E123-E198.
27. Manchikanti L, Helm S, Singh V, Benyamin RM, Datta S, Hayek S, Fellows B, Boswell MV. An algorithmic approach for clinical management of chronic spinal pain. *Pain Physician* 2009; 12:E225-E264.
28. Atluri S, Datta S, Falco FJE, Lee M. Systematic review of diagnostic utility and therapeutic effectiveness of thoracic facet joint interventions. *Pain Physician* 2008; 11:611-629.
29. Falco FJE, Erhart S, Wargo BW, Bryce DA, Atluri S, Datta S, Hayek SM. Systematic review of diagnostic utility and therapeutic effectiveness of cervical facet joint interventions. *Pain Physician* 2009; 12:323-344.
30. Datta S, Lee M, Falco FJE, Bryce DA, Hayek SM. Systematic assessment of diagnostic accuracy and therapeutic utility of lumbar facet joint interventions. *Pain Physician* 2009; 12:437-460.
31. Singh V, Manchikanti L, Shah RV, Dunbar EE, Glaser SE. Systematic review of thoracic discography as a diagnostic test for chronic spinal pain. *Pain Physician* 2008; 11:631-642.
32. Wolfer L, Derby R, Lee JE, Lee SH. Systematic review of lumbar provocation discography in asymptomatic subjects with a meta-analysis of false-positive rates. *Pain Physician* 2008; 11:513-538.
33. Manchikanti L, Dunbar EE, Wargo BW, Shah RV, Derby R, Cohen SP. Systematic review of cervical discography as a diagnostic test for chronic spinal pain. *Pain Physician* 2009; 12:305-321.
34. Manchikanti L, Glaser S, Wolfer L, Derby R, Cohen SP. Systematic review of lumbar discography as a diagnostic test for chronic low back pain. *Pain Physician* 2009; 12:541-559.
35. Conn A, Buenaventura R, Datta S, Abdi S, Diwan S. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009; 12:109-135.

36. Parr AT, Diwan S, Abdi S. Lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain: A systematic review. *Pain Physician* 2009; 12:163-188.
37. Benyamin RM, Singh V, Parr AT, Conn A, Diwan S, Abdi S. Systematic review of the effectiveness of cervical epidurals in the management of chronic neck pain. *Pain Physician* 2009; 12:137-157.
38. Buenaventura RM, Datta S, Abdi S, Smith HS. Systematic review of therapeutic lumbar transforaminal epidural steroid injections. *Pain Physician* 2009; 12:233-251.
39. Helm S, Hayek S, Benyamin RM, Manchikanti L. Systematic review of the effectiveness of thermal annular procedures in treating discogenic low back pain. *Pain Physician* 2009; 12:207-232.
40. Smith HS, Chopra P, Patel VB, Frey ME, Rastogi R. Systematic review on the role of sedation in diagnostic spinal interventional techniques. *Pain Physician* 2009; 12:195-206.
41. Frey ME, Manchikanti L, Benyamin RM, Schultz DM, Smith HS, Cohen SP. Spinal cord stimulation for patients with failed back surgery syndrome: A systematic review. *Pain Physician* 2009; 12:379-397.
42. Epter RS, Helm S, Hayek SM, Benyamin RM, Smith HS, Abdi S. Systematic review of percutaneous adhesiolysis and management of chronic low back pain in post lumbar surgery syndrome. *Pain Physician* 2009; 12:361-378.
43. Patel VB, Manchikanti L, Singh V, Schultz DM, Hayek SM, Smith HS. Systematic review of intrathecal infusion systems for long-term management of chronic non-cancer pain. *Pain Physician* 2009; 12:345-360.
44. Rupert MP, Lee M, Manchikanti L, Datta S, Cohen SP. Evaluation of sacroiliac joint interventions: A systematic appraisal of the literature. *Pain Physician* 2009; 12:399-418.
45. Hayek SM, Helm S, Benyamin RM, Singh V, Bryce DA, Smith HS. Effectiveness of spinal endoscopic adhesiolysis in post lumbar surgery syndrome: A systematic review. *Pain Physician* 2009; 12:419-435.
46. Hirsch JA, Singh V, Falco FJE, Benyamin RM, Manchikanti L. Automated percutaneous lumbar discectomy for the contained herniated lumbar disc: A systematic assessment of evidence. *Pain Physician* 2009; 12:601-620.
47. Singh V, Manchikanti L, Benyamin RM, Helm S, Hirsch JA. Percutaneous lumbar laser disc decompression: A systematic review of current evidence. *Pain Physician* 2009; 12:573-588.
48. Singh V, Benyamin RM, Datta S, Falco FJE, Helm S, Manchikanti L. Systematic review of percutaneous lumbar mechanical disc decompression utilizing Dekompressor. *Pain Physician* 2009; 12:589-599.
49. Manchikanti L, Derby R, Benyamin RM, Helm S, Hirsch JA. A systematic review of mechanical lumbar disc decompression with nucleoplasty. *Pain Physician* 2009; 12:561-572.
50. Haynes RB, Sackett RB, Gray JMA, Cook DC, Guyatt GH. Transferring evidence from research into practice, 1: The role of clinical care research evidence in clinical decisions. *ACP J Club* 1996; 125:A14-A16.
51. Guyatt G, Drummond R. Part 1. The basics: Using the medical literature. 1A. Introduction: The philosophy of evidence-based medicine. In: *Users' Guides to the Medical Literature. A Manual for Evidence-Based Clinical Practice*. The Evidence-Based Medicine Working Group. AMA Press, 2002, pp 3-12.
52. Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E (eds); Committee on Standards for Systematic Reviews of Comparative Effectiveness Research; Institute of Medicine. *Clinical Practice Guidelines We Can Trust*. The National Academies Press, Washington, DC, 2011.
53. Eden J, Levit L, Berg A, Morton S (eds); Committee on Standards for Systematic Reviews of Comparative Effectiveness Research; Institute of Medicine. *Finding What Works in Health Care. Standards for Systematic Reviews.* The National Academies Press, Washington, DC, 2011.
54. Manchikanti L, Helm II S, Hirsch JA. The evolution of the Patient-Centered Outcome Research Institute. *J Neurointervent Surg* 2011; Published Online First: 31 August 2011.

55. Manchikanti L, Giordano J, Fellows B, Hirsch JA. Placebo and nocebo in interventional pain management: A friend of a foe – or simply foes? *Pain Physician* 2011; 14:E157-E175.
56. Carette S, Marcoux S, Truchon R, Grondin C, Gagnon J, Allard Y, Latulippe M. A controlled trial of corticosteroid injections into facet joints for chronic low back pain. *N Engl J Med* 1991; 325:1002-1007.
57. Carette S, Leclaire R, Marcoux S, Morin F, Blaise GA, St-Pierre A, Truchon R, Parent F, Levesque J, Bergeron V, Montminy P, Blanchette C. Epidural corticosteroid injections for sciatica due to herniated nucleus pulposus. *N Engl J Med* 1997; 336:1634-1640.
58. Karppinen J, Malmivaara A, Kurunlahti M, Kyllönen E, Pienimäki T, Nieminen P, Ohinmaa A, Tervonen O, Vanharanta H. Periradicular infiltration for sciatica: A randomized controlled trial. *Spine (Phila Pa 1976)* 2001; 26:1059-1067.
59. Gupta R, Shah M, Reese CM. Steroid induced spinal epidural lipomatosis--case report and review of the literature. *W V Med J* 2011; 107:20-22.
60. Tachihara H, Sekiguchi M, Kikuchi S, Konno S. Do corticosteroids produce additional benefit in nerve root infiltration for lumbar disc herniation. *Spine (Phila Pa 1976)* 2008; 33:743-747.
61. Sato C, Sakai A, Ikeda Y, Suzuki H, Sakamoto A. The prolonged analgesic effect of epidural ropivacaine in a rat model of neuropathic pain. *Anesth Analg* 2008; 106:313-320.
62. Pham Dang C, Lelong A, Guilley J, Nguyen JM, Volteau C, Venet G, Perrier C, Lejus C, Blanloeil Y. Effect on neurostimulation of injectates used for perineural space expansion before placement of a stimulating catheter: Normal saline versus dextrose 5% in water. *Reg Anesth Pain Med* 2009; 34:398-403.
63. Tsui BC, Kropelin B, Ganapathy S, Finucane B. Dextrose 5% in water: Fluid medium maintaining electrical stimulation of peripheral nerve during stimulating catheter placement. *Acta Anaesthesiol Scand* 2005; 49:1562-1565.
64. Pasqualucci A, Varrassi G, Braschi A, Peduto VA, Brunelli A, Marinangeli F, Gori F, Colò F, Paladín A, Mojoli F. Epidural local anesthetic plus corticosteroid for the treatment of cervical brachial radicular pain: Single injection verus continuous infusion. *Clin J Pain* 2007; 23:551-557.
65. Lavoie PA, Khazen T, Filion PR. Mechanisms of the inhibition of fast axonal transport by local anesthetics. *Neuropharmacology* 1989; 28:175-181.
66. Bisby MA. Inhibition of axonal transport in nerves chronically treated with local anesthetics. *Exp Neurol* 1975; 47:481-489.
67. Cassuto J, Sinclair R, Bonderovic M. Anti-inflammatory properties of local anesthetics and their present and potential clinical implications. *Acta Anaesthesiol Scand* 2006; 50:265-282.
68. Manchikanti L, Cash KA, McManus CD, Pampati V, Smith HS. One year results of a randomized, double-blind, active controlled trial of fluoroscopic caudal epidural injections with or without steroids in managing chronic discogenic low back pain without disc herniation or radiculitis. *Pain Physician* 2011; 14:25-36.
69. Manchikanti L, Singh V, Cash KA, Pampati V, Damron KS, Boswell MV. A randomized, controlled, double-blind trial of fluoroscopic caudal epidural injections in the treatment of lumbar disc herniation and radiculitis. *Spine (Phila Pa 1976)* 2011; 36:1897-1905.
70. Manchikanti L, Singh V, Cash KA, Pampati V, Datta S. Management of pain of post lumbar surgery syndrome: One-year results of a randomized, double double-blind, active controlled trial of fluoroscopic caudal epidural injections. *Pain Physician* 2010; 13:509-521.
71. Manchikanti L, Cash RA, McManus CD, Pampati V, Fellows B. Fluoroscopic caudal epidural injections with or without steroids in managing pain of lumbar spinal stenosis: One year results of randomized, double-blind, active-controlled trial. *J Spinal Disord* 2011; April 5 [Epub ahead of print].
72. Manchikanti L, Singh V, Falco FJE, Cash KA, Pampati V. Evaluation of the effectiveness of lumbar interlaminar epidural injections in managing chronic pain of lumbar disc herniation or radiculitis: A randomized, double-blind, controlled trial. *Pain Physician* 2010; 13:343-355.

73. Manchikanti L, Cash KA, McManus CD, Pampati V, Benyamin RM. Preliminary results of a randomized, double-blind, controlled trial of fluoroscopic lumbar interlaminar epidural injections in managing chronic lumbar discogenic pain without disc herniation or radiculitis. *Pain Physician* 2010; 13:E279-E292.
74. Manchikanti L, Cash KA, McManus CD, Damron KS, Pampati V, Falco FJE. Lumbar interlaminar epidural injections in central spinal stenosis: Preliminary Results of a randomized, double-blind, active control trial. *Pain Physician* 2012; 15:51-63.
75. Manchikanti L, Cash KA, Pampati V, Wargo BW, Malla Y. Cervical epidural injections in chronic discogenic neck pain without disc herniation or radiculitis: Preliminary results of a randomized, double-blind, controlled trial. *Pain Physician* 2010; 13:E265-E278.
76. Manchikanti L, Cash KA, Pampati V, Wargo BW, Malla Y. The effectiveness of fluoroscopic cervical interlaminar epidural injections in managing chronic cervical disc herniation and radiculitis: Preliminary results of a randomized, double-blind, controlled trial. *Pain Physician* 2010; 13:223-236.
77. Manchikanti L, Malla Y, Cash KA, McManus CD, Pampati V. Fluoroscopic epidural injections in cervical spinal stenosis: Preliminary results of a randomized, double-blind, active control trial. *Pain Physician* 2012; 15:E59-E70.
78. Manchikanti L, Malla Y, Cash KA, McManus CD, Pampati V. Fluoroscopic cervical interlaminar epidural injections in managing chronic pain of cervical post-surgery syndrome: Preliminary results of a randomized, double-blind active control trial. *Pain Physician* 2012; 15:13-26.
79. Manchikanti L, Cash KA, McManus CD, Pampati V, Benyamin RM. A preliminary report of a randomized double-blind, active controlled trial of fluoroscopic thoracic interlaminar epidural injections in managing chronic thoracic pain. *Pain Physician* 2010; 13:E357-E369.
80. Manchikanti L, Singh V, Falco FJE, Cash KA, Pampati V. Evaluation of lumbar facet joint nerve blocks in managing chronic low back pain: A randomized, double-blind, controlled trial with a 2-year follow-up. *Int J Med Sci* 2010; 7:124-135.
81. Manchikanti L, Singh V, Falco FJE, Cash KA, Fellows B. Comparative outcomes of a 2-year follow-up of cervical medial branch blocks in management of chronic neck pain: A randomized, double-blind controlled trial. *Pain Physician* 2010; 13:437-450.
82. Manchikanti L, Singh V, Falco FJE, Cash KA, Pampati V, Fellows B. Comparative effectiveness of a one-year follow-up of thoracic medial branch blocks in management of chronic thoracic pain: A randomized, double-blind active controlled trial. *Pain Physician* 2010; 13:535-548.
83. Ghahreman A, Ferch R, Bogduk N. The efficacy of transforaminal injection of steroids for the treatment of lumbar radicular pain. *Pain Med* 2010; 11:1149-1168.
84. Cigna Government Services. LCD for Pain Management (L31845). Revision Effective Date: 10/17/2011. www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=31845&ContrId=228&ver=11&ContrVer=2&CntrctrSelected=228*2&Cntrctr=228&name=CGS+Administrators%2c+LLC+(15102%2c+MAC+-+Part+B)&DocStatus=Active&s=22&bc=AggAAAIAAAAA&
85. Armon C, Argoff CE, Samuels J, Backonja MM; Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Assessment: Use of epidural steroid injections to treat radicular lumbosacral pain: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology* 2007; 68:723-729.
86. American Society of Anesthesiologists Task Force on Chronic Pain Management; American Society of Regional Anesthesia and Pain Medicine. Practice guidelines for chronic pain management: An updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology* 2010; 112:810-833.
87. Staal JB, de Bie RA, de Vet HC, Hildebrandt J, Nelemans P. Injection therapy for subacute and chronic low back pain: An updated Cochrane review. *Spine (Phila Pa 1976)* 2009; 34:49-59.

88. National Government Services, Inc. LCD for Pain Management (L28529). Revision Effective Date 10/01/2010. www.ngsmedicare.com/wps/poc/ngsmedicare?urile=wcm:path:/NGSMedicareContent/NGSMedicare/Coverage%20Determination/Medical%20Policy%20Center/L28529&LOB=Part+A
89. Dashfield AK, Taylor MB, Cleaver JS, Farrow D. Comparison of caudal steroid epidural with targeted steroid placement during spinal endoscopy for chronic sciatica: A prospective, randomized, double-blind trial. *Br J Anaesth* 2005; 94:514-559.
90. Bush K, Hillier S. A controlled study of caudal epidural injections of triamcinolone plus procaine for the management of intractable sciatica. *Spine (Phila Pa 1976)* 1991; 16:572-575.
91. Mathews JA, Mills SB, Jenkins VM, Grimes SM, Morkel MJ, Mathews W, Scott CM, Sittampalam Y. Back pain and sciatica: Controlled trials of manipulation, traction, sclerosant and epidural injections. *Brit J Rheumatol* 1987; 26:416-423.
92. Hesla PE, Breivik H. Epidural analgesia and epidural steroid injection for treatment of chronic low back pain and sciatica. *Tidsskr Nor Laegeforen* 1979; 99:936-939.
93. Breivik H, Hesla PE, Molnar I, Lind B. Treatment of chronic low back pain and sciatica. Comparison of caudal epidural injections of bupivacaine and methylprednisolone with bupivacaine followed by saline. In: Bonica JJ, Albe-Fesard D (eds). *Advances in Pain Research and Therapy*. Raven Press, New York, 1976, pp 927-932.
94. Sayegh FE, Kenanidis EI, Papavasiliou KA, Potoupnis ME, Kirkos JM, Kapetanos GA. Efficacy of steroid and nonsteroid caudal epidural injections for low back pain and sciatica: A prospective, randomized, double-blind clinical trial. *Spine (Phila Pa 1976)* 2009; 34:1441-1447.
95. Manchikanti L, Singh V, Cash KA, Pampati V, Damron KS, Boswell MV. A randomized, controlled, double-blind trial of fluoroscopic caudal epidural injections in the treatment of lumbar disc herniation and radiculitis. *Spine (Phila Pa 1976)* 2011; 36:1897-1905.
96. Ackerman WE 3rd, Ahmad M. The *efficacy* of *lumbar epidural steroid injections* in *patients* with *lumbar disc herniations*. *Anesth Analg* 2007; 104:1217-1222.
97. McCahon RA, Ravenscroft A, Hodgkinson V, Evley R, Hardman J. A *pilot study* of the *dose-response* of *caudal methylprednisolone* with *levobupivacaine* in *chronic lower back pain*. *Anaesthesia* 2011; 66:595-603.
98. Makki D, Nawabi DH, Francis R, Hamed AR, Hussein AA. Is the *outcome* of *caudal epidural injections affected* by *patient positioning*? *Spine (Phila Pa 1976)* 2010; 35:E687-E690.
99. Mendoza-Lattes S, Weiss A, Found E, Zimmerman B, Gao Y. *Comparable effectiveness* of *caudal vs*. *trans-foraminal* epidural *steroid injections*. *Iowa Orthop J* 2009; 29:91-96.
100. Iversen T, Solberg TK, Romner B, Wilsgaard T, Twisk J, Anke A, Nygaard O, Hasvold T, Ingebrigtsen T. *Effect* of *caudal epidural steroid* or *saline injection* in *chronic lumbar* radiculopathy: multicentre, blinded, randomised controlled trial. *BMJ* 2011; 343:d5278.
101. Manchikanti L, Pampati V, Cash KA. Protocol for evaluation of the comparative effectiveness of percutaneous adhesiolysis and caudal epidural steroid injections in low back and/or lower extremity pain without post surgery syndrome or spinal stenosis. *Pain Physician* 2010; 13:E91-E110.
102. Revel M, Auleley GR, Alaoui S, Nguyen M, Duruoz T, Eck-Michaud S, Roux C, Amor B. Forceful epidural injections for the treatment of lumbosciatic pain with post-operative lumbar spinal fibrosis. *Rev Rhum Engl Ed* 1996; 63:270-277.
103. Manchikanti L, Cash RA, McManus CD, Pampati V, Fellows B. Fluoroscopic caudal epidural injections with or without steroids in managing pain of lumbar spinal stenosis: One year results of randomized, double-blind, active-controlled trial. *J Spinal Disord* 2011; April 5 [Epub ahead of print]..
104. Ciocon JO, Galindo-Ciocon D, Amaranath L, Galindo D. Caudal epidural blocks for elderly patients with lumbar canal stenosis. *J Am Geriatr Soc* 1994; 42:593-596.
105. Botwin K, Brown LA, Fishman M, Rao S. Fluoroscopically guided caudal epidural steroid injections in degenerative lumbar spine stenosis. *Pain Physician* 2007; 10:547-558.

106. Manchikanti L, Pampati V, Rivera JJ, Beyer C, Damron K, Barnhill R. Caudal epidural injections with Sarapin or steroids in chronic low back pain. *Pain Physician* 2001; 4:322-335.
107. Manchikanti L, Singh V, Rivera JJ, Pampati V, Beyer CD, Damron KS, Barnhill RC. Effectiveness of caudal epidural injections in discogram positive and negative chronic low back pain. *Pain Physician* 2002; 5:18-29.
108. Manchikanti L, Cash KA, McManus CD, Damron KS, Pampati V, Falco FJE. Lumbar interlaminar epidural injections in central spinal stenosis: Preliminary Results of a randomized, double-blind, active control trial. *Pain Physician* 2012; 15:51-64.
109. Candido KD, Raghavendra MS, Chinthagada M, Badiee S, Trepashko DW. A prospective evaluation of iodinated contrast flow patterns with fluoroscopically guided lumbar epidural steroid injections: the lateral parasagittal interlaminar epidural approach versus the transforaminal epidural approach. *Anesth Analg* 2008; 106:638-644.
110. Lee JH, An JH, Lee SH. Comparison of the effectiveness of interlaminar and bilateral transforaminal epidural steroid injections in treatment of patients with lumbosacral disc herniation and spinal stenosis. *Clin J Pain* 2009; 25:206-210.
111. Rados I, Sakic K, Fingler M, Kapural L. Efficacy of interlaminar vs. transforaminal epidural steroid injection for the treatment of chronic unilateral radicular pain: Prospective, randomized study. *Pain Med* 2011; 12:1316-1321.
112. Manchikanti L, Cash KA, Pampati V, Wargo BW, Malla Y. Cervical epidural injections in chronic discogenic neck pain without disc herniation or radiculitis: Preliminary results of a randomized, double-blind, controlled trial. *Pain Physician* 2010; 13:E265-E278.
113. Castagnera L, Maurette P, Pointillart V, Vital JM, Erny P, Senegas J. Long term results of cervical epidural steroid injection with and without morphine in chronic cervical radicular pain. *Pain* 1994; 58:239-243.
114. Stav A, Ovadia L, Sternberg A, Kaadan M, Weksler N. Cervical epidural steroid injection for cervicobrachialgia. *Acta Anaesthesiol Scand* 1993; 37:562-566.
115. Riew KD, Yin Y, Gilula L, Bridwell KH, Lenke LG, Lauryssen C, Goette K. The effect of nerve-root injections on the need for operative treatment of lumbar radicular pain. A prospective, randomized, controlled, double-blind study. *J Bone Joint Surg Am* 2000; 82-A:1589-1593.
116. Riew KD, Park JB, Cho YS, Gilula L, Patel A, Lenke LG, Bridwell KH. Nerve root blocks in the treatment of lumbar radicular pain. A minimum five-year follow-up. *J Bone Joint Surg Am* 2006; 88:1722-1725.
117. Jeong HS, Lee JW, Kim SH, Myung JS, Kim JH, Kang HS. Effectiveness of transforaminal epidural steroid injection by using a preganglionic approach: A prospective randomized controlled study. *Radiology* 2007; 245:584-590.
118. Vad VB, Bhat AL, Lutz GE, Cammisa F. Transforaminal epidural steroid injections in lumbosacral radiculopathy: A prospective randomized study. *Spine (Phila Pa 1976)* 2002; 27:11-16.
119. Ng L, Chaudhary N, Sell P. The efficacy of corticosteroids in periradicular infiltration for chronic radicular pain. A randomized, double-blind, controlled trial. *Spine (Phila Pa 1976)* 2005; 30:857-862
120. Park CH, Lee SH, Kim BI. Comparison of the effectiveness of lumbar transforaminal epidural injection with particulate and nonparticulate corticosteroids in lumbar radiating pain. *Pain Med* 2010; 11:1654-1658.
121. Tafazal S, Ng L, Chaudhary N, Sell P. Corticosteroids in peri-radicular infiltration for radicular pain: A randomised double blind controlled trial. One year results and subgroup analysis. *Eur Spine J* 2009; 18:1220-1225.