

American Society of Interventional Pain Physicians

" The Voice of Interventional Pain Management "

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RE: Epidural and Facet Joint Interventions for Spinal Pain

Dr. Bearmord,

On behalf of the American Society of Interventional Pain Physicians (ASIPP), we would like to thank you for publishing multiple updated medical policies for minimally invasive treatment of back and neck pain and would like to provide comments. The primary objective of these comments are to ensure that these procedures are provided appropriately and that patients insured by United Healthcare maintain access to care. We are hopeful that you will reconsider the policies and re-evaluate the evidence.

ASIPP is a not-for-profit professional organization comprised of 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 sub acute, 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).

There are multiple concerns about United Healthcare policy in reference to epidural steroid injections/selective nerve root blocks, facet joint injections, adhesiolysis, and radiofrequency neurotomy procedures.

1.0 EPIDURAL STEROID INJECTIONS AND SELECTIVE NERVE ROOT BLOCKS

The policy states:

Epidural steroid injection is proven for the treatment of acute and sub-acute sciatica or radicular pain of the low back caused by spinal stenosis, disc herniation or degenerative changes in the vertebrae.

Epidural steroid injections have a clinically established role in the short-term management of low back pain when the following two criteria are met:

- The pain is associated with symptoms of nerve root irritation and/or low back pain due to disc extrusions and/or contained herniations AND
- The pain is unresponsive to conservative treatment, including but not limited to pharmacotherapy, exercise or physical therapy.

Epidural steroid injection is unproven for all other indications of the lumbar spine.

There is a lack of evidence from randomized controlled trials indicating that epidural steroid injections effectively treat patients with lumbar pain not associated with sciatica or radicular pain.

Your policy does not cover long-term, repeated, or therapeutic epidural steroid injection/selective nerve root block for any indication because it is considered not medically necessary. However, evidence is contrary to the policy as illustrated below. Consequently, we request that United Healthcare change its policy based on the evidence and Medicare LCDs, etc., as illustrated below.

Further, indications should be defined separately as the evidence is variable for disc herniation and radiculitis, discogenic pain, post-laminectomy syndrome, spinal stenosis, and technique-caudal, interlaminar, transforaminal, and per region cervical and thoracic, lumbar and sacral.

The ASIPP guidelines and multiple systematic reviews (11,18,20-24) of caudal epidural injections, lumbar interlaminar epidural injections, lumbar transforaminal epidural injections, and cervical interlaminar epidural injections showed variable evidence based on each condition (25-29).

1.1 Caudal Epidural Injections

Conn et al (21) 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, post-lumbar 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 post-lumbar 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 (30-35). Another manuscript was published (36) which was not included in this analysis. The only study included in Conn et al's (21) analysis by Manchikanti et al (30) was performed with fluoroscopic visualization. As illustrated in the updated table, which also includes the newer studies or excluded studies from Conn et al (21), show positive results, specifically when they were performed under fluoroscopy (30,31,37,39-42), whereas all the negative studies were performed without fluoroscopy including the most recent one by Iversen et al (38), which was performed with ultrasound with a multitude of flaws in their inclusion criteria and analysis, along with imaging.

Table 1. Results of randomized trials of 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 2008,2011 (30,37)	RA, DB, F	120	77% vs. 80%	77% vs 82%	70% to 77%	<i>P</i>	<i>P</i>
Dashfield et al 2005 (31)	RA, DB, F	Caudal = 30 Endoscopy = 30	SI	SI	NA	<i>P</i>	NA
Bush and Hillier 1991 (32)	RA, DB, B	23	SI	NSI	NSI	<i>P</i>	N
Mathews et al 1987 (33)	RA, DB	C = 34 T = 23	SI	SI	SI	N	<i>P</i>
Hesla and Breivik 1979 (34)	RA, DB	69 patients: crossover design	77% vs 29%	59% vs 25%	59% vs 25%	<i>P</i>	<i>P</i>
Breivik et al 1976 (35)	RA, DB, B	C = 19 T = 16	20% vs 50%	20% vs 50%	NA	<i>P</i>	NA
Iversen et al (38)	R, PC, B	116	N	N	N	U	U
Ackerman & Ahmad (39)	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	<i>P</i>	NA
McCahon et al (40)	R, AC, B	33	SI in 40 mg group	NA	NA	<i>P</i>	NA
Makki et al (41)	R, AC, F	57	SI in lateral group	NA	NA	<i>P</i>	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 (21).

Conn et al (21) showed the evidence of randomized trials in managing low back pain of post-lumbar 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 (43). Table 3 shows the evidence in spinal stenosis was also similar to post lumbar surgery syndrome with Level II-1 or Level II-2, with only study being performed under fluoroscopy (44). Table 4 illustrates results of studies of 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 post-surgery 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 2008,2010 (43,45)	RA, DB, F	40	65% to 70%	60%	60% to 65%	P	P
Revel et al 1996 (46)	RA, B	Forceful injection = 29 Regular = 31	NA	49% vs 19%	NA	P	P
Hesla and Breivik 1979 (34)	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 (21).

Table 3. Results of effectiveness in evaluation in 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 2008, 2011 (44,47)	RA, DB, F	40	50% to 65%	60% to 65%	55% to 65%	P	P
Ciocon et al 1994 (48)	O, B	30	SI	SI	NA	P	NA
Botwin et al 2007 (49)	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 (21).

Table 4. Results of randomized and observational studies of 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 2008, 2011 (50,51)	RA, DB, F	64	78%	75% to 81%	72%	P	P
Manchikanti et al 2001 (52)	O, F	70	95%	85%	61% to 73%	P	P
Manchikanti et al 2002 (53)	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 (21).

1.2 Interlaminar Epidural Injections

As shown repeatedly, multiple systematic reviews provided negative opinions for lumbar interlaminar epidural injections. However, 2 systematic reviews performed evaluating lumbar and cervical interlaminar epidurals (22,23). They arrived at conflicting conclusions with systematic review of the effectiveness of the cervical epidurals in the management of chronic neck pain illustrating Level II-1 evidence in managing chronic neck and upper extremity pain (23), whereas, the evidence if Level II-2 for short-term relief of pain of disc herniation or radiculitis utilizing blind interlaminar epidural steroid injections with 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 (54,55). The evidence for blind lumbar interlaminar epidurals in disc herniation and radiculitis is negative (22). 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 post-surgery 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 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 in 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 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 (56)	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 (57)	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 (58)	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 (59)	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 (60)	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 (61)	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 (62)	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 (23) 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 post cervical surgery 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 post surgery 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 (63)	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 (64)	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 (65)	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 (66)	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 (67)	RA	Local anesthetic with steroids =14 Local anesthetic with steroids and morphine =10	79%	79%	79%	P	P
Stav et al 1993 (68)	RA	C = 17 T = 25	12% vs 68%	12% vs 68%	12% vs 68%	P	P
Pasqualucci et al 2007 (69)	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 (23).

1.3 Lumbar Transforaminal Epidural Injections

The systematic review by Buenaventura et al (24) 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 effectiveness of lumbar transforaminal epidural injections.

Table 7. Results of randomized trials of 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 2001/2001 (70,71)	RA, DB	C = 80 T = 80	SICH	NSI	NSI	P	N
Riew et al 2000/ 2006 (72,73)	P, RA, DB	55	NA	NA	33% vs. 71% (avoided surgery)	P	P
Jeong et al 2007 (74)	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 (75)	RA	48	NA	NA	48% vs. 84%	P	P
Ghahreman et al 2010 (21)	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 (22)	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 (61)	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 (39)	RA, AC	90	Caudal = 17 of 30 (57%) Interlaminar=18 of 30 (60%) Transforaminal=25 of 30 (83%)	Caudal = 17 of 30 (57%) Interlamina r=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 (59)	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 (26)	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 (62)	RA, AC	64	TF=53% IL=75%	TF=53% IL=75%	NA	P	NA
Tafazal et al 2009 (28)	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 (24).

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
 - Post lumbar surgery 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 are same as for caudal epidural injections, except for post-surgery syndrome.
- Caudal epidural is the modality of choice for post-surgery syndrome.
- ◆ Common indications for cervical interlaminar are as follows:
- Chronic neck and/or upper extremity pain which has failed to respond or poorly responded to non-interventional and non-surgical conservative management resulting from:
 - Herniated, protruded, or extruded disc with or without radiculitis
 - Cervical spinal stenosis
 - Post cervical surgery 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 are as follows:
- Chronic mid back or upper back pain which has failed to respond or poorly responded to non-interventional and non-surgical conservative management resulting from:
 - Herniated, protruded, or extruded disc with or without radiculitis
 - Thoracic spinal stenosis
 - Thoracic post-surgery 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 non-interventional and non-surgical conservative management
- Chronic low back and/or lower extremity pain resulting from:
 - Disc herniation/radiculitis
 - FBSS without extensive scar tissue and hardware
 - Spinal stenosis with radiculitis
 - Discogenic pain with radiculitis

Frequency of Interventions

- ◆ Guidelines of 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.

Manchikanti et al (81,82) showed that utilizing Chou and Huffman's criteria, the evidence appears to be fair, based on grading of good, fair, and poor in managing lumbar nerve root pain with transforaminal epidural injections. Consequently, our reassessment has shown multiple deficiencies in their analysis and inappropriate conclusions.

In summary, there is significant evidence now with repeat injections appropriately performed under fluoroscopy for all types of lumbar epidural injections, even though it is emerging for lumbar interlaminar epidural injections.

There is also evidence for cervical epidural injections which appears to be fair even with old studies. Thus, permitting cervical epidural injections is also appropriate, specifically with new evidence (56,57). Further, there is also moderate evidence at the present time for thoracic epidural injections (83).

Manchikanti et al (83) demonstrated the effectiveness of thoracic interlaminar epidural injections in chronic function-limiting thoracic pain in 80% of the patients receiving local anesthetic only and 85% of patients receiving local anesthetic and steroids utilizing an average of 3-4 procedures per year.

2.0 FACET JOINT INJECTIONS AND ABLATIVE TREATMENT

We agree with your criteria for diagnostic facet joint injections; however, it does not show what is allowed for controlled diagnostic blocks and how you interpret the positive response.

Further, it is very concerning that therapeutic facet joint injections for the treatment of chronic neck or back pain are not covered at all.

United Healthcare covers a diagnostic facet joint injection (CPT codes 64490-64495) as medically necessary when used to localize the source of pain to the facet joint in persons with spinal pain:

United Healthcare does not cover therapeutic facet joint injection (CPT codes 64490-64495) for the treatment of chronic spinal pain.

United Healthcare does not cover diagnostic or therapeutic facet joint injection with ultrasound guidance (CPT codes 0213T-0218T) for any indication because it is considered experimental, investigational, or unproven.

In reference to radiofrequency neurotomy, the indications are somewhat difficult to follow. Even then they are considered appropriate but, your claims department may have been refusing some of these. Consequently, we emphasize to please look into various aspects of all facet joint interventions.

Further, cost effectiveness is same - either you perform therapeutic facet joint injections in appropriately diagnosed patients with performance of therapeutic facet joint nerve blocks or radiofrequency neurotomy with proper diagnosis. In addition, it will be appropriate to have separate limits for multiple regions rather than the same limit for the entire spine.

United Healthcare covers initial radiofrequency ablation/neurolysis of paravertebral facet joint nerves (CPT codes 64622-64627, 77003) for the treatment of chronic back or neck pain as medically necessary when ALL of the following criteria are met:

- temperature 60 degrees Celsius or more
- duration of ablation 40-90 seconds
- positive response to medial branch block injection at the side and level of the proposed ablation, AND
- confirmation of needle placement by fluoroscopic guided imaging

United Healthcare covers repeat radiofrequency ablation/neurolysis of paravertebral facet joint nerves at the same level for the treatment of chronic back or neck pain as medically necessary when BOTH of the following criteria are met:

- At a frequency of six months or longer (maximum of 2 times over a 12 month period), AND
- provided there has been a 50% or greater documented reduction in pain for 10 to 12 weeks.

2.1 Diagnosis of Cervical Facet Joint Pain

Cervical intervertebral discs, facet joints, ligaments, fascia, muscles, and nerve root dura have been shown to be capable of transmitting pain in the cervical spine with resulting symptoms of neck pain, upper extremity pain, and headache (84-89). The diagnostic blocks applied in the precision diagnosis of chronic neck pain include cervical facet joint nerve blocks, and cervical provocation discography (84,86).

Diagnostic Cervical Facet or Zygapophysial Joint Blocks

The rationale for using facet joint blocks for diagnosis is based on the fact that cervical facet joints are capable of causing pain and they have a nerve supply (90-93). Facet joints have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity (84,85,94-103). The value, validity, and clinical effectiveness of diagnostic facet joint nerve blocks has also been illustrated by the application of therapeutic modalities based on the diagnosis with controlled comparative local anesthetic blocks (84,85,104-110).

The face validity of cervical medial branch or facet joint nerve blocks has been established by injecting small volumes of local anesthetic and contrast material onto the target points for these structures and by determining the spread of contrast medium in the posteroanterior and lateral radiographs (18,84,85,92). Construct validity of facet joint blocks is important to eliminate placebo effect as the source of confounding results and to secure true-positive results (18,84,85,94-103). The hypothesis that testing a patient first with lidocaine and subsequently with bupivacaine provides a means of identifying the placebo response has been tested and proven (18,84,85,111-113).

Potential and real confounding factors were assessed in several studies. Influence of age, surgery, psychopathology, and prior opioid exposure were evaluated in 3 reports and found not to have significant impact on the prevalence of cervical facet joint related chronic neck pain (100,114-118).

Based on the systematic review by Falco et al (84) diagnostic cervical facet joint nerve blocks, utilizing 9 studies (94-97,99-103) meeting inclusion criteria with 80% pain relief and ability to perform previously painful movements with controlled diagnostic blocks, estimated the prevalence as 36% to 67% with CIs ranging from 27% to 75% in patients in heterogenous population with an average of 49% with 95% CI of 45% to 52%. In addition, the prevalence was shown to be 36% with 95% CI of 22% to 51% in patients after surgical intervention (100).

Based on the systematic review by Falco et al (84), false-positive rates with a single block or 27% to 63% with CIs ranging from 15% to 78% with an average of 49% with 95% CI of 44% to 54% (Table 8).

Table 8. Data of prevalence and false-positive rates of cervical diagnostic facet joint blocks.

Study	# of Subjects	Prevalence Estimates	False-Positive Rate
Barnsley et al 1995 (102)	50	54% (95% CI, 40%, 68%).	NA
Barnsley et al 1993 (103)	55	NA	27% (95% CI, 15%, 38%)
Lord et al 1996 (101)	68	60% (95% CI, 46%, 73%)	NA
Manchikanti et al 2002 (97)	120	67% (95% CI, 58%, 75%)	63% (95% CI 48%, 78%)
Manchikanti et al 2004 (96)	255 of 500	55% (95% CI, 49%, 61%)	63% (95% CI 54%, 72%)
Manchukonda et al 2007 (95)	251 of 500	39% (95% CI, 32%, 45%)	45% (95% CI 37%, 52%)
Manchikanti et al 2008 (100)	Non-Surgery: 206	Non-Surgery 39% (95% CI, 33%, 46%)	Non-Surgery 43% (95% CI 35%, 52%)
	Post-Surgery: 45	Post-Surgery 36% (95% CI, 22%, 51%)	Post-Surgery 50% (95% CI 32%, 68%)
Speldewinde et al 2001 (99)	97	36% (95% CI, 27%, 45%)	NA
Yin and Bogduk 2008 (94)	84 of 143	42%# (95% CI, 31%, 52%)	NA
OVERALL	980	49% (95% CI, 45%, 52%)	49% (95% CI, 44%, 54%)

Authors reported adjusted prevalence as 55% (95% CI, 38%, 62%) and crude prevalence as 24%.

NA = not available or not applicable; CI = confidence interval

Source: Falco FJE et al. Systematic review of diagnostic utility and therapeutic effectiveness of cervical facet joint interventions. *Pain Physician* 2009; 12:323-344 (84).

Further, Rubinstein and van Tulder (119), publishers of multiple Cochrane reviews, in a best evidence review of diagnostic procedures for neck pain concluded that there is strong evidence for the diagnostic accuracy of cervical facet joint blocks in evaluating spinal pain.

Based on the true evidence-based guidelines (18,84,85,111,119-121), diagnostic cervical facet joint nerve blocks are recommended in patients with suspected facet joint pain.

In summary, based on the overwhelming evidence, the diagnostic cervical facet joint nerve blocks have been validated and approved by numerous agencies and almost all insurers. Thus, 2 diagnostic facet joint nerve blocks must be performed prior to embarking onto therapeutic phase. The therapeutic phase starts after completion of the 2 diagnostic facet joint blocks, that is essentially a third visit for interventional procedures.

Indications for diagnostic cervical facet joint nerve blocks include:

- ◆ Patients suffering with somatic or non-radicular neck pain or headache and upper extremity pain, with duration of pain of at least 3 months.
- ◆ Average pain levels of greater than 6 on a scale of 0 to 10.
- ◆ Pain is at least intermittent or continuous causing functional disability.
- ◆ Problem has failed to respond and has not resolved with more conservative management, including physical therapy modalities with exercises, chiropractic management, and non-steroidal anti-inflammatory agents.
- ◆ Lack of preponderance of evidence of discogenic pain, disc herniation, or evidence of radiculitis.
- ◆ There is no evidence of contraindications for the needle placement and injection of local anesthetics.
- ◆ Contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate non-steroidal anti-inflammatory drugs.

- ◆ A positive response is based on the following evidence:
 - Patient has met the above indications.
 - Patient responds positively to controlled local anesthetic blocks either with placebo control or comparative local anesthetic blocks with appropriate response to each local anesthetic with < 1 mL of local anesthetic.
 - At least 80% relief as criterion standard with ability to perform previously painful movement without deterioration of the relief (i.e., extension, overhead activity, lateral rotation, flexion, etc.).
 - The patient's response should be recorded independently by the assessor - generally a registered nurse familiar with patient or another physician.

2.2 Diagnosis of Thoracic Facet Joint Pain

Thoracic intervertebral discs, facet joints, ligaments, fascia, muscles, and nerve root dura have been shown to be capable of transmitting pain in the thoracic spine with resulting symptoms of thoracic pain (18,111,122-124). The diagnostic blocks applied in the precision diagnosis of chronic thoracic pain include thoracic facet joint nerve blocks, and thoracic provocation discography (18,111,122-124).

Diagnostic Thoracic Facet or Zygapophysial Joint Blocks

The rationale for using facet joint blocks for diagnosis is based on the fact that thoracic facet joints are capable of causing pain and they have a nerve supply (18,111,122,123,125-128). Facet joints have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity (18,95,96,111,122,123,125-129). The value, validity, and clinical effectiveness of diagnostic facet joint nerve blocks has also been illustrated by the application of therapeutic modalities based on the diagnosis with controlled comparative local anesthetic blocks in the cervical and lumbar spine in general and thoracic spine in particular (18,122,123,125,130-132).

The face validity of thoracic medial branch or facet joint nerve blocks has been established by injecting small volumes of local anesthetic and contrast material onto the target points for these structures and by determining the spread of contrast medium in the posteroanterior and lateral radiographs (18,95,96,111,122,123,129). Construct validity of facet joint blocks is important to eliminate placebo effect as the source of confounding results and to secure true-positive results (18,95,96,111,122,123,129). The hypothesis that testing a patient first with lidocaine and subsequently with bupivacaine provides a means of identifying the placebo response has been tested and proven (18,111-113,122,123,133,134).

The validity of comparative local anesthetic blocks was determined not only by short-term relief with controlled diagnostic blocks, and ability to perform movements which were painful prior to the blocks, but also with application of another appropriate reference standard (long-term follow-up) as described in the literature (135-138). Utilizing the modified criteria established by the International Association for the Study of Pain (IASP), false-positive rates varying from 42% to 55% were demonstrated. Minimal effect of sedation in cervical and lumbar spine (116,117,139); and lack of influence of psychological factors on the validity of controlled thoracic diagnostic local anesthetic blocks of facet joints was demonstrated (114). Other variables including prior opioid exposure were also evaluated (115,140,141).

Based on the systematic review by Atluri et al (123) utilizing 3 studies (95,96,129), utilizing the criteria of controlled local anesthetic blocks, with 80% pain relief, the prevalence was estimated as 34% to 42% with a 95% CIs ranging from 22% to 53% (Table 9). They also showed the false-positive rates of single local anesthetic blocks to range from 42% to 55% with CIs ranging from 26% to 78%.

Table 9. Data of prevalence with controlled diagnostic blocks and false-positive rates in thoracic region.

Study	Participants	Prevalence	False-Positive Rate
Manchikanti et al 2002 (129)	46	48% (95% CI 34%–62%)	58% (95% CI 38%–78%)
Manchikanti et al 2004 (95)	72	42% (95% CI 30%–53%)	55% (95% CI 39%–78%)
Manchukonda et al 2007 (96)	65	34% (95% CI 22%–47%)	42% (95% CI 26%–59%)

AHRQ=Agency for Healthcare Research and Quality; CI = confidence interval

The evidence for the diagnosis of thoracic facet joint pain with controlled comparative local anesthetic blocks has been determined as Level II-1 or II-2 based on USPSTF criteria (131). Further, Rubinstein and van Tulder (119) in a best evidence review of diagnostic procedures for spinal pain concluded that their evidence was strong for the diagnostic accuracy of spinal facet joint blocks in evaluating spinal pain. These authors are very well known in Cochrane review process with numerous publications.

The recommendations are as follows:

Based on true evidence-based guidelines (18,62,63,92,103,115) diagnostic thoracic facet joint nerve blocks are recommended in patients with suspected facet joint pain.

In summary, based on the overwhelming evidence, the diagnostic thoracic facet joint nerve blocks have been validated and approved by numerous agencies and almost all insurers. Thus, 2 diagnostic facet joint nerve blocks must be performed prior to embarking onto therapeutic phase. The therapeutic phase starts after completion of the 2 diagnostic facet joint blocks, that is essentially a third visit for interventional procedures.

- ◆ Indications for diagnostic thoracic facet joint nerve blocks include:
 - Patients suffering with somatic or non-radicular mid back, upper back, or chest wall pain, with duration of pain of at least 3 months.
 - Average pain levels are of greater than 6 on a scale of 0 to 10.
 - Pain is at least intermittent or continuous causing functional disability.
 - Condition has failed to respond to more conservative management, including physical therapy modalities with exercises, chiropractic management, and non-steroidal anti-inflammatory agents.
 - Lack of preponderance of evidence of discogenic pain and lack of disc herniation or evidence of radiculitis.
 - No evidence of contraindications is present for the needle placement and injection of local anesthetics.
 - Presence of contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate non-steroidal anti-inflammatory drugs.

- ◆ A positive response is based on the following evidence:
 - Patient has met the above indications.
 - Patient responds positively to controlled local anesthetic blocks either with placebo control or comparative local anesthetic blocks with appropriate response to each local anesthetic of < 1 mL for each nerve or joint.

- At least 80% relief as criterion standard with the ability to perform previously painful movement without deterioration of the relief (i.e., extension, lateral rotation, flexion, etc.).
- The patient's response should be recorded independently by an assessor – generally a registered nurse familiar with the patient or another physician.

2.3 Diagnosis of Lumbar Facet Joint Pain

Lumbar intervertebral discs, facet joints, sacroiliac joint, ligaments, fascia, muscles, and nerve root dura have been shown to be capable of transmitting pain in the lumbar spine with resulting symptoms of low back pain and lower extremity pain (18,122). The diagnostic blocks applied in the precision diagnosis of chronic low back pain include lumbar facet joint nerve blocks and lumbar provocation discography.

Diagnostic Lumbar Facet or Zygapophysial Joint Blocks

The rationale for using facet joint blocks for diagnosis is based on the fact that lumbar facet joints are capable of causing pain and they have a nerve supply (18,90,122,142-147). Facet joints have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity (18,85,95-97,111,122,148-155). The value, validity, and clinical effectiveness of diagnostic facet joint nerve blocks has also been illustrated by the application of therapeutic modalities based on the diagnosis with controlled comparative local anesthetic blocks (18,85,122,156,157).

The face validity of lumbar medial branch or facet joint nerve blocks has been established by injecting small volumes of local anesthetic and contrast material onto the target points for these structures and by determining the spread of contrast medium in the posteroanterior and lateral radiographs (18,85,111,122). Construct validity of facet joint blocks is important to eliminate placebo effect as the source of confounding results and to secure true-positive results (18,85,111,122,133). The hypothesis that testing a patient first with lidocaine and subsequently with bupivacaine provides a means of identifying the placebo response has been tested and proven (111-113,133,134).

The specificity of the effect of lumbar facet joint blocks was demonstrated in controlled trials (158,159). Provocation response of facet joint pain was shown to be unreliable in one study (160).

The validity of comparative local anesthetic blocks was determined not only by short-term relief with controlled diagnostic blocks, and ability to perform movements which were painful prior to the blocks, but also with application of another appropriate reference standard (long-term follow-up) as described in the literature (135-137,160). Utilizing the modified criteria established by the International Association for the Study of Pain (IASP), false-positive rates varying from 17% to 50% were demonstrated. Minimal effect of sedation (116,139) and lack of influence of psychological factors on the validity of controlled lumbar diagnostic local anesthetic blocks of facet joints was demonstrated (114,161). Other variables including prior opioid exposure were also evaluated (115,140,141).

Based on the systematic review by Datta et al (85), prevalence is 21% to 40% in heterogenous population with chronic low back pain and 16% in post lumbar surgery syndrome with confidence intervals (CIs) ranging from 9% to 23% in post surgery syndrome and 14% to 53% in heterogenous population (Table 1). The overall prevalence is 31% (95% CI; 28%–33%).

Based on Datta et al's (85) systematic review, false-positive rates of 17% to 49% are demonstrated with CIs ranging from 10% to 59% with overall false-positive rate of 30% (95% CI 27%-33%) (Table 10).

Table 10. Data of prevalence with controlled diagnostic blocks and false-positive rates in the lumbar region.

Study	Participants	Prevalence	False-Positive Rate
Manchikanti et al 2002 (97)	120	40% (95% CI 31%–49%)	30% (95% CI 20%–40%)
Manchikanti et al 2004 (96)	397	31% (95% CI 27%–36%)	27% (95% CI 22%–32%)
Manchukonda et al 2007 (95)	303	27% (95% CI 22%–33%)	45% (95% CI 36%–53%)
Schwarzer et al 1995 # (154)	63	40% (95% CI 29%–53%)	NA
Manchikanti et al 2001 (162)	120	40% (95% CI 31%–49%)	47% (95% CI 35%–59%)
Manchikanti et al 2003 (151)	300	I. 21% (95% CI 14%–27%) II. 41% (95% CI 33%–49%)	I. 17% (95% CI 10%–24%) II. 27% (95% CI 18%–36%)
Manchikanti et al 2007 (155)	117	16% (95% CI 9%–23%)	49% (95% CI 39%–59%)
Overall	1,420	31% (95% CI; 28%–33%)	30%# (95% CI; 27%–33%)

CI = confidence interval; NA =not available; # Schwarzer et al (152) was without evaluation of false-positive rates.

*Methodologic quality assessment adapted and modified from West S, et al. Systems to Rate the Strength of Scientific Evidence, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. 02-E016 (163).

Evidence is Level I or II-1 based on the (USPSTF) criteria (163). Rubinstein and van Tulder (119) in a best-evidence review of diagnostic procedures for low-back pain concluded that there is strong evidence for the diagnostic accuracy of lumbar facet joint blocks in evaluating spinal pain. It should be recognized that Rubinstein and van Tulder are heavily involved in Cochrane guideline synthesis and are considered as methodologic gurus in evidence-based medicine.

The recommendations are as follows:

Based on true evidence-based guidelines (18,120-122) diagnostic lumbar facet joint nerve blocks are recommended in patients with suspected facet joint pain.

In summary, based on the overwhelming evidence, the diagnostic lumbar facet joint nerve blocks have been validated and approved by numerous agencies and almost all insurers. Thus, 2 diagnostic facet joint nerve blocks must be performed prior to embarking onto therapeutic phase. The therapeutic phase starts after completion of the 2 diagnostic facet joint blocks, that is essentially a third visit for interventional procedures.

- ◆ Indications for diagnostic lumbar facet joint nerve blocks include:
 - Patients suffering with somatic or non-radicular low back and lower extremity pain, with duration of pain of at least 3 months.
 - Average pain levels are of greater than 6 on a scale of 0 to 10.
 - Pain is at least intermittent or continuous causing functional disability.
 - Condition has failed to respond to more conservative management, including physical therapy modalities with exercises, chiropractic management, and non-steroidal anti-inflammatory agents.
 - Lack of preponderance of evidence of either lumbar discogenic or sacroiliac joint pain and lack of lumbar disc herniation or evidence of radiculitis.
 - No evidence of contraindications is present for the needle placement and injection of local anesthetics.
 - Presence of contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate non-steroidal anti-inflammatory drugs.

- ◆ A positive response is based on the following evidence:
 - Patient has met the above indications.
 - Patient responds positively to controlled local anesthetic blocks either with placebo control or comparative local anesthetic blocks with appropriate response to each local anesthetic of < 1 mL for each nerve or joint.
 - At least 80% relief as criterion standard with the ability to perform previously painful movement without deterioration of the relief (i.e., extension, lateral rotation, flexion, etc.).
 - The patient's response should be recorded independently by an assessor – generally a registered nurse familiar with the patient or another physician.

2.4 Therapeutic Lumbar Facet Joint Interventions

Once the diagnosis of facet joint pain is proven, there are 3 modalities of treatments available. These include intraarticular injections, medial branch blocks, and radiofrequency neurotomy.

Based on the available evidence, therapeutic intraarticular facet joint injections are not recommended.

With reference to medial branch blocks:

Table 11. Results of published randomized trials of lumbar facet joint interventions.

Study	Study Characteristics	Participants	Pain Relief				Results	
			≤ 3 mos.	3 mos.	6 mos.	12 mos.	Short-term ≤ 6 mos.	Long-term > 6 mos.
Manchikanti et al 2001 (165)	RA	Group I non-steroid = 32 Group II steroid = 41	100%	75% versus 88%	75% versus 88%	NA	P	NA
Manchikanti et al 2008, 2010 (157,166)	RA, DB	Group I – no steroid = 60 Group II – steroid = 60	NA	83% vs 82%	83% vs 93%	82% vs 85%	P	P
Nath et al 2008 (156)	RA, DB	C = 20 * T = 20	NA	SI	SI	NA	P	NA
van Wijk et al 2005 (168)	RA, DB	C = 41 * T = 40	NA	39% versus 62%	NA	NA	P	NA
van Kleef et al 1999 (169)	RA, DB	C = 16 * T = 15	NA	25% vs 60%	19% vs 47%	13% vs 47%	P	N
Gallagher et al 1994 (170)	RA, DB	C = 12 * T = 18	SI = T	SI = T	SI = T	NA	P	NA
Leclaire et al 2001 (171)	RA, DB	C = 34 * T = 36	NSI	NSI	NA	NA	NA	NA
Tekin et al 2007 (172)	RA, DB	C = 20 * PRF = 20 CRF = 20	SI in all groups	SI in all groups	SI in all groups	SI in CRF only	P	P

* = control included bupivacaine; RA = randomized; DB = double blind; NS = not scored by APS-AAPM review; C = control; T = treatment; vs = versus; SI = significant improvement; NSI = no significant improvement; P = positive; SH = sodium hyaluronate; TA = triamcinolone acetonide; NA = not available; SB = single blind; PRF = pulsed radiofrequency; CRF = conventional radiofrequency

Source: Manchikanti L, et al. A critical review of the American Pain Society clinical practice guidelines for interventional techniques: Part 2. Therapeutic interventions. *Pain Physician* 2010, 13:E215-E264 (121).

As of now, there are 2 randomized trials of facet joint nerve blocks have been published (157,165) meeting the methodological assessment criteria. However, Chou and Huffman (173) concluded that there was no trial evaluating the efficacy of therapeutic medial branch blocks versus sham or placebo injection. They also included 2 trials which evaluated the short-term relief of medial branch blocks (167,174). Neither of them was relevant to chronic low back pain management. Both studies compared facet joint

nerve blocks and intraarticular injections with high volume injections with very short-term follow-up. Both the studies by Manchikanti et al (157,165) were shown to be of high quality even though one study (157,166) with 2 reports was not included in the analysis by Chou and Huffman (173), despite its publication prior to the search (175).

Manchikanti et al (166) in a randomized, double-blind, controlled trial included 60 patients in Group I with local anesthetic and 60 patients in Group II with local anesthetic and steroid. This study rated high utilizing even Chou et al's criteria. The results utilizing multiple outcome measures such as numeric pain scores and Oswestry Disability Index (ODI) showed significant pain relief of greater than 50% and functional status improvement of at least 40% in 82% in Group I and 85% in Group II. The results of the same study were published with a 2-year follow-up (157) which illustrated the sustainability of the results showing significant improvement observed in 85% of the patients in Group I and 90% in Group II with a total of 5 to 6 treatments, an average relief of 19 weeks per episode of treatment, and patients experiencing significant pain relief 82 to 84 weeks out of 104 weeks. Consequently, this is the longest follow-up study of a controlled, randomized, double blind trial for therapeutic lumbar facet joint nerve blocks using strict criteria.

The cost effectiveness of lumbar facet joint nerve blocks has been established. The procedures are safe. Indications are described for diagnostic facet joint nerve blocks. For therapeutic interventions, the diagnosis must be established with a positive response to controlled local anesthetic blocks with 80% relief. However, 80% pain relief is not expected in the therapeutic phase, it is 50% with appropriate duration of 8 to 12 weeks.

Among the studies evaluating radiofrequency neurotomy, only one study by Nath et al (156) was ideal and met the inclusion criteria by other evaluators (176). However, Chou et al found multiple deficiencies with this study which was previously considered one of the best studies in the literature except for lack of long-term follow-up. Chou et al misinterpreted Nath et al's data (146). Chou and Huffman reported that the final scores in both groups were identical and there was no change in low back pain; however, Nath et al (156) showed clear and distinct differences between both groups in all aspects. The active treatment group showed statistically significant improvement, not only in back and leg pain, but also back and hip movement as well as sacroiliac joint pain. There was also significant improvement in quality of life variables, global perception of improvement, and generalized pain in the active treatment group. Further, they also used conflicting numbers in their document stating in one place that there were 40 patients and in another, 60 patients, with the actual number being 40 patients (121,173,175,178,179).

Chou et al also included multiple studies which failed to meet inclusion criteria by others. These were by Gallagher et al (170), van Kleef et al (169), Leclaire et al (171), van Wijk et al (168), and Tekin et al (172). Surprisingly, the authors of these studies had conflicting opinions and Leclaire et al (171) have recanted their results and recommended the study must not be used for clinical purposes (180).

The indicated level of evidence for therapeutic lumbar facet joint nerve blocks is Level II-1 or II-2. The recommendation is strong (1B or 1C) for the use of therapeutic lumbar facet joint nerve blocks to provide both short-term and long-term relief in the treatment of chronic facet joint pain.

The indicated evidence is Level II-2 to II-3 for lumbar radiofrequency neurotomy. For lumbar radiofrequency neurotomy, the recommendation is 1C/strong recommendation.

Recommended frequency of interventions based upon ASIPP guidelines and also approved by multiple insurers including Medicare are as follows:

- ◆ In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary according to the medical necessity criteria, and it is suggested that these be limited to 4 times for local anesthetic and steroid blocks over a period of one year, per region.
- ◆ For radiofrequency neurotomy of lumbar facet joint nerves, the suggested frequency would be 6 months or longer (maximum of 2 times per year) between each procedure, provided that 50% or greater relief is obtained for 4 to 6 months, per region.

2.5 Therapeutic Cervical Facet Joint Interventions

Once the diagnosis of facet joint pain is proven, there are 3 modalities of treatments available. These include intraarticular injections, medial branch blocks, and radiofrequency neurotomy.

Based on the available evidence, therapeutic intraarticular facet joint injections are not recommended.

With reference to medial branch blocks:

Table 12. *Published results of studies of cervical medial branch blocks.*

Study	Study Characteristics	No. of Patients		Long-term Relief			Results	
				3 mos.	6 mos.	12 mos.	24 mos.	Short-term relief ≤ 6 mos.
CERVICAL								
Manchikanti et al 2008 (104), 2010 (105)	RA, DB	Group I = 60 Group II = 60	83% vs 85%	87% vs 95%	85% vs 92%	85% vs. 93%	P	P
Manchikanti et al 2004 (106)	O	100	92%	82%	56%	N/A	P	P

RA = randomized; DB = Double-blind; O = observational; vs = versus; P = positive; N = negative; N/A = not applicable

At present in the literature one well performed randomized double-blind has been published in 3 publications (104,105) with one-year publication, and 2-year publication. There is also one prospective evaluation (106). Falco et al (84) reviewed the evidence from all the available medial branch blocks and included a randomized and observational study in their evaluation (106).

Manchikanti et al (104) in the publication of one-year follow-up of a randomized, double-blind, controlled trial evaluated a total of 120 patients with 60 patients in each of the local anesthetic and steroid groups. All of the patients met the diagnostic criteria of cervical facet joint pain by means of comparative, controlled diagnostic blocks, and the inclusion criteria. The results showed significant pain relief (> 50%) and functional status improvement was observed at 3 months, 6 months, and 12 months in over 83% of the patients. The average number of treatments per year was 3.5 ± 1.0 in the non-steroid group and 3.4 ± 0.9 in the steroid group. Duration of average pain relief with each procedure was 14 to 16 weeks. Significant relief and functional improvement was reported for 46 to 48 weeks in one-year. They concluded that therapeutic cervical medial branch nerve blocks with or without steroids, may provide effective management for chronic neck pain of facet joint origin.

They also published the 2-year results (105). The 2-year results showed 85% of patients in Group I and 93% of patients in Group II showed significant pain relief (> 50%) at 2 years. The average number of treatments for 2 years was 5.7. The duration of average relief with each procedure was 17 to 19 weeks on average in both groups. Significant improve of pain and function was demonstrated for 83 to 89 weeks over a period of 2 years.

Table 13. *Published results of studies of cervical facet joint nerve neurotomy.*

Study	Study Characteristics	Number of Patients	Pain Relief (months)		Results	
			6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Cervical						
Lord et al 1996 (107)	RA, DB	24-control 24-active	♦ 1 of sham ♦ 7 of active	58% in active treatment group	P	P
Sapir and Gorup 2001 (108)	O	46	NA	Mean VAS change 4.6 ± 1.8	P	P
McDonald et al 1999 (109)	O	28	NA	71%	P	P
Barnsley 2005 (110)	O	35	NA	74%	P	P

RA = randomized; DB = double blind; O = Observational; NA = not available; VAS = visual analog scale; P = positive; N = negative

Source: Falco FJE et al. Systematic review of diagnostic utility and therapeutic effectiveness of cervical facet joint interventions. *Pain Physician* 2009; 12:323-344 (84).

With reference to radiofrequency neurotomy: for cervical radiofrequency neurotomy there was only one randomized trial which met inclusion criteria (107), and 3 observational studies (107-110).

In 1996, Lord et al (107) evaluated the effectiveness of percutaneous radiofrequency neurotomy for chronic cervical zygapophyseal joint pain in a randomized, double-blind clinical trial with strict diagnostic selection criteria in 24 patients. At 3 months all patients were interviewed by completing the visual-analogue scale, the McGill Pain Questionnaire (MPQ), side effects, complications, and any sensation of numbness. At 27 weeks, one patient in the control group and 7 in the active treatment group remained free of pain. The median time for return of pain to at least 50% of the pre-operative level was 263 days in the active group and 8 days in the placebo group. This study found that radiofrequency neurotomy can provide pain relief for a moderate proportion of patients lasting from months to over a year.

Among the 2 observational studies, Sapir and Gorup (108) evaluated patients with neck pain after whiplash and showed no significant difference among the patients with or without litigation. The second study was by Barnsley (110) assessing outcomes in a series of consecutive patients with percutaneous radiofrequency neurotomy of chronic neck pain showing positive results. A third study was performed by McDonald et al (109), and similar to the one performed by Barnsley (110) produced positive results.

The cost effectiveness of cervical facet joint nerve blocks has not been established. However, cervical facet joint nerve blocks will be much more cost effective than radiofrequency neurotomy considering 2 procedures per year for radiofrequency neurotomy and 4 procedures per year for cervical facet joint nerve blocks, because, cervical radiofrequency neurotomy cannot be performed bilaterally in the same session. Since a large number of patients do suffer with bilateral cervical facet joint pain, they will be receiving one procedure at a time, thus resulting in 4 radiofrequency neurotomies per year rather than 2 in lumbar spine, which is equivalent to the number of cervical medial branch blocks, increasing the cost substantially.

Based on USPSTF criteria (164), the indicated evidence for cervical medial branch blocks is Level II-1 or II-2 with a strong recommendation of 1B or 1C.

The indicated evidence is Level II-1 to II-2 for cervical radiofrequency neurotomy. For cervical radiofrequency neurotomy, the recommendation is 1C/strong recommendation.

Recommended frequency of interventions based upon ASIPP guidelines and also approved by multiple insurers including Medicare are as follows:

- ◆ In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary according to the medical necessity criteria, and it is suggested that these be limited to 4 times for local anesthetic and steroid blocks over a period of one year, per region.
- ◆ For radiofrequency neurotomy of cervical facet joint nerves, the suggested frequency would be 6 months or longer (maximum of 2 times per year) between each procedure, provided that 50% or greater relief is obtained for 4 to 6 months, per region.

2.6 Therapeutic Thoracic Facet Joint Interventions

Once the diagnosis of facet joint pain is proven, there are 3 modalities of treatments available. These include intraarticular injections, medial branch blocks, and radiofrequency neurotomy.

Based on the available evidence, therapeutic intraarticular facet joint injections and radiofrequency neurotomy are without published evidence.

With reference to medial branch blocks:

Three studies have been published evaluating the therapeutic role of medial branch blocks (105-107).

Table 14. Results of published reports of effectiveness of thoracic medial branch blocks.

Study	Study Characteristics	No. of Patients	Long-term Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008, 2010 (130,131)	RA, DB	Group I - no steroid=50 Group II - steroid=50	94% vs 96%	94% vs 94%	90% vs 90%	P	P
Manchikanti et al 2006 (132)	O	55	71%	71%	76%	P	P

RA = randomized; DB = Double-blind; O = observational; vs = versus; P = positive; N = negative

Based on the quality of evidence using USPSTF criteria (156) the indicated level of evidence for thoracic facet nerve blocks is Level II-2 with a strong (1C) recommendation (18,122,123).

Recommended frequency of interventions based upon ASIPP guidelines and also approved by multiple insurers including Medicare are as follows:

- ◆ In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary according to the medical necessity criteria, and it is suggested that these be limited to 4 times for local anesthetic and steroid blocks over a period of one year, per region.

3.0 PERCUTANEOUS ADHESIOLYSIS

It appears based on the policy, percutaneous adhesiolysis is not a covered service.

United Healthcare does not cover ANY of the following procedures because each is considered experimental, investigational or unproven (this list may not be all-inclusive):

- automated percutaneous lumbar discectomy (APLD)/automated percutaneous nucleotomy (CPT code 62287, HCPCS codes C2614)
- Coblation[®] Nucleoplasty[™], disc nucleoplasty, decompression nucleoplasty plasma disc decompression (CPT code 62287)
- devices for annular repair (e.g., Inclose[™] Surgical Mesh System, Xclose[™] Tissue Repair System (Anulex Technologies, Inc., Minnetonka, MN))
- endoscopic epidural adhesiolysis (CPT code 64999)
- epiduroscopy, epidural myeloscopy, epidural spinal endoscopy (CPT code 64999)
- intervertebral disc biacuplasty (CPT code 22899)
- intradiscal electrothermal annuloplasty (e.g., intradiscal electrothermal therapy [IDET[™]])
- percutaneous laminotomy/laminectomy, percutaneous spinal decompression (e.g., mild[®] procedure) (CPT codes 22899, 64999, 0274T, 0275T, HCPCS code C9729))
- percutaneous laser discectomy /decompression, laser-assisted disc decompression (LADD) (CPT code 62287)
- percutaneous epidural adhesiolysis, percutaneous epidural lysis of adhesions, Racz procedure (CPT codes 62263, 62264)
- percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), intradiscal radiofrequency thermomodulation or percutaneous radiofrequency thermomodulation (CPT codes 22526, 22527, HCPCS code S2348)

The purpose of percutaneous adhesiolysis is to eliminate the deleterious effects of scar formation, which can physically prevent direct application of drugs to nerves or other tissues to treat chronic back pain with or without radiculopathy, and to assure target delivery of drugs.

The technique of lumbar adhesiolysis involves accessing the lumbar epidural space either by utilizing a caudal, interlaminar, or transforaminal approach. Entry is performed with a 16-gauge RK needle, followed by advancement of a Racz catheter into the epidural space, with appropriate lysis of adhesions under radiographic control utilizing nonionic contrast medium. Subsequently, a combination of local anesthetic and steroid is injected into the epidural space through the catheter; followed by hypertonic saline neurolysis which is carried out by a slow and intermittent injection of hypertonic saline, either by infusion or in incremental doses. In classic Racz technique, the procedure is repeated without steroids on Day 2 and Day 3; whereas, with other modifications, the catheter is removed after performing the initial procedure.

ASIPP guidelines (18) and systematic review performed by Epter et al (181) utilizing 7 studies (182-188), 3 of which were randomized (182-184), concluded that the indicated level of evidence is I or II-1 for short- and long-term relief of percutaneous adhesiolysis in post-lumbar surgery syndrome. At the time of this systematic review no evidence was available for spinal stenosis.

Table 15 shows the evidence synthesis for post-laminectomy syndrome. In addition to this, stronger evidence is available now with 2 randomized trials evaluating either post-surgery syndrome or spinal stenosis (189,190). In the study of post-lumbar surgery syndrome, Manchikanti et al (189) in a randomized double-blind trial evaluated 60 patients in each group showing significant improvement of

pain ($\geq 50\%$) and function ($\geq 40\%$) with Oswestry in 73% of patients compared to 12% in the caudal epidural group with catheter positioned at S3.

Table 15. Results of randomized trials of effectiveness of percutaneous lysis of lumbar epidural adhesions.

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term ≤ 6 mos.	Long-term >6 mos.
Manchikanti et al 2009 (189)	RA	Caudal = 60 (control) Adhesiolysis = 60 (intervention)	Caudal = 35% Adhesiolysis = 90%	Caudal = 18% Adhesiolysis = 85%	Caudal = 12% Adhesiolysis = 73%	P	P
Manchikanti et al 2009 (190)	RA	Caudal = 25 (control) Adhesiolysis = 25 (intervention)	Caudal = 28% Adhesiolysis = 80%	Caudal = 12% Adhesiolysis = 80%	Caudal = 4% Adhesiolysis = 76%	P	P
Manchikanti et al 2004 (182)	RA, DB	Control = 25 Adhesiolysis only = 25 Adhesiolysis + 10% NaCl = 25	Control = 0% Adhesiolysis only = 64% Adhesiolysis + 10% NaCl = 72%	Control = 0% Adhesiolysis only = 60% Adhesiolysis + 10% NaCl = 72%	Control = 0% Adhesiolysis only = 60% Adhesiolysis + 10% NaCl = 72%	P	P
Heavner et al 1999 (183)	RA, DB	59	49%	43%	49%	P	P
Veihelmann et al 2006 (184)	RA	99	SI	SI	SI	P	P

RA = randomized; DB = double blind; O = observational; G = group; SI = significant improvement; P = positive; N = negative

Adapted and modified from: Epter RS et al. Systematic review of percutaneous adhesiolysis and management of chronic low back pain in post lumbar surgery syndrome. *Pain Physician* 2009; 12:361-378 (181).

Spinal stenosis also has been studied in a randomized, double-blind, controlled trial (183). The preliminary results of 25 patients in each group showed significant pain relief ($> 50\%$) in 76% of the patients at one year follow-up in the adhesiolysis group compared to 4% of the patients in the control group. They concluded with significant pain relief in 76% of patients, percutaneous adhesiolysis utilizing local anesthetic, steroids, and hypertonic sodium chloride solution may be effective in patients with chronic function-limiting low back and lower extremity pain with spinal stenosis.

Thus percutaneous adhesiolysis on a one-day protocol may be approved when the patients meet appropriate indications and medical necessity is documented.

Further, the indications for percutaneous adhesiolysis are as follows:

- ◆ Common indications are as follows:
 - Chronic low back and/or lower extremity pain resulting from:
 - Failed back surgery syndrome/epidural fibrosis
 - Spinal stenosis

- Disc herniation with radiculitis
- Duration of pain of at least 6 months.
- Intermittent or continuous pain causing functional disability.
- Average pain levels of ≥ 6 on a scale of 0 to 10.
- Failure to respond or poor response to noninterventional and non-surgical conservative management and fluoroscopically-directed epidural injections
- Absence of facet joint pain determined by controlled local anesthetic blocks

Recommend frequency for percutaneous adhesiolysis is as follows:

- ◆ The number of procedures are preferably limited to:
 - 4 interventions per year, with a one-day protocol.

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.

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.



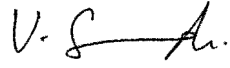
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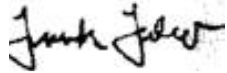
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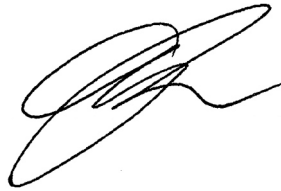
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REFERENCES

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. 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.
4. 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.
5. Revel M, Poiraudau S, Auleley GR, Payan C, Denke A, Nguyen M, Chevrot A, Fermanian J. Capacity of the clinical picture to characterize low back pain relieved by facet joint anesthesia. Proposed criteria to identify patients with painful facet joints. *Spine (Phila Pa 1976)* 1998; 23:1972-1976.
6. 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.
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. Chou R, Huffman L. *Guideline for the Evaluation and Management of Low Back Pain: Evidence Review*. American Pain Society, Glenview, IL, 2009.
www.ampainsoc.org/pub/pdf/LBPEvidRev.pdf
10. Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical interventional therapies for low back pain: A review of the evidence for an American Pain Society clinical practice guideline. *Spine (Phila Pa 1976)* 2009; 34:1078-1093.
11. Chou R, Loeser JD, Owens DK, Rosenquist RW, Atlas SJ, Baisden J, Carragee EJ, Grabojs M, Murphy DR, Resnick DK, Stanos SP, Shaffer WO, Wall EM; American Pain Society Low Back Pain Guideline Panel. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society. *Spine (Phila Pa 1976)* 2009; 34:1066-1077.
12. 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.
13. 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.
14. 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.
15. 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.

16. Peer Review, Public and Washington State Agency Comments and Responses for *Spinal Injections* Health Technology Assessment, Washington State Health Care Authority. Spectrum Research, Inc., December 14, 2010.
17. 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.
18. 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.
19. 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.
20. 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.
21. 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.
22. 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.
23. 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.
24. Buenaventura RM, Datta S, Abdi S, Smith HS. Systematic review of therapeutic lumbar transforaminal epidural steroid injections. *Pain Physician* 2009; 12:233-251.
25. Manchikanti L, Boswell MV, Giordano J. Re: Friedly J, Chan L, Deyo R. Increases in lumbosacral injections in the Medicare population: 1994 to 2001. *Spine (Phila PA 1976)* 2007; 32:1754-1760. *Spine (Phila PA 1976)* 2007; 32:3092.
26. Manchikanti L, Jasper J, Singh V. Cochrane Review by Nelemans et al. *Spine (Phila PA 1976)* 2001; 26:2641-2643.
27. Manchikanti L, Singh V. Are the results of a multicenter analysis of radiofrequency denervation success as a function of single diagnostic block reliable? *Spine J* 2009; 9:704-705.
28. Manchikanti L, Singh V. Periradicular infiltration for sciatica. *Spine (Phila PA 1976)* 2002; 27:335-336.
29. Manchikanti L, Boswell MV, Giordano J, Kaplan E. 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; 69:1190.
30. Manchikanti L, Singh V, Cash KA, Pampati V, Damron KS, Boswell MV. Preliminary results of randomized, equivalence trial of fluoroscopic caudal epidural injections in managing chronic low back pain: Part 2. Disc herniation and radiculitis. *Pain Physician* 2008; 11:801-815.
31. 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.
32. 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.

33. 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.
34. 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.
35. 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-Fessard D (eds). *Advances in Pain Research and Therapy*. Raven Press, New York, 1976, pp 927-932.
36. 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.
37. 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.
38. 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.
39. Ackerman WE 3rd, Ahmad M. The efficacy of lumbar epidural steroid injections in patients with lumbar disc herniations. *Anesth Analg* 2007; 104:1217-1222.
40. 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.
41. 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.
42. 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.
43. Manchikanti L, Singh V, Cash KA, Pampati V, Datta S. Preliminary results of randomized, equivalence trial of fluoroscopic caudal epidural injections in managing chronic low back pain: Part 3. Post surgery syndrome. *Pain Physician* 2008; 11:817-831.
44. Manchikanti L, Cash KA, McManus CD, Pampati V, Abdi S. Preliminary results of randomized, equivalence trial of fluoroscopic caudal epidural injections in managing chronic low back pain: Part 4. Spinal stenosis. *Pain Physician* 2008; 11:833-848.
45. 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.
46. 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.
47. 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; in press.
48. 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.
49. 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.
50. Manchikanti L, Cash KA, McManus CD, Pampati V, Smith HS. Preliminary results of randomized, equivalence trial of fluoroscopic caudal epidural injections in managing chronic low back pain: Part 1. Discogenic pain without disc herniation or radiculitis. *Pain Physician* 2008; 11:785-800.

51. 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.
52. 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.
53. 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.
54. 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.
55. 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.
56. 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.
57. 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.
58. 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.
59. 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.
60. Ackerman WE 3rd, Ahmad M. The efficacy of lumbar epidural steroid injections in patients with lumbar disc herniations. *Anesth Analg* 2007; 104:1217-1222.
61. 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.
62. 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.
63. 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.
64. 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.
65. 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.
66. 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.

67. 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.
68. Stav A, Ovadia L, Sternberg A, Kaadan M, Weksler N. Cervical epidural steroid injection for cervicobrachialgia. *Acta Anaesthesiol Scand* 1993; 37:562-566.
69. Pasqualucci A, Varrassi G, Braschi A, Peduto VA, Brunelli A, Marinangeli F, Gori F, Colò F, Paladini A, Mojoli F. Epidural local anesthetic plus corticosteroid for the treatment of cervical brachial radicular pain: Single injection versus continuous infusion. *Clin J Pain* 2007; 23:551-557.
70. 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.
71. Karppinen J, Ohinmaa A, Malmivaara A, Kurunlahti M, Kyllönen E, Pienimäki T, Nieminen P, Tervonen O, Vanharanta H. Cost effectiveness of periradicular infiltration for sciatica: Subgroup analysis of a randomized controlled trial. *Spine (Phila Pa 1976)* 2001; 26:2587-2595.
72. Riew KD, Yin Y, Gilula L, Bridwell KH, Lenke LG, Laurysen 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.
73. 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.
74. 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.
75. 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.
76. 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.
77. 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.
78. Ackerman WE 3rd, Ahmad M. The efficacy of lumbar epidural steroid injections in patients with lumbar disc herniations. *Anesth Analg* 2007; 104:1217-1222.
79. 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.
80. 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.
81. 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.
82. 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.
83. 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.

84. 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.
85. 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.
86. 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.
87. Peloso PMJ, Gross A, Haines T, Trinh K, Goldsmith CH, Burnie SJ, Cervical Overview Group. Medicinal and injection therapies for mechanical neck disorders. *Cochrane Database Syst Rev* 2007; 3:CD000319.
88. Saskatchewan Workers' Compensation Board. Statistical Supplement 2005. www.wcsask.com/WCBPortal/ShowProperty/WCBRepository/formsPublications/publications/annualPubs/2005StatisticalSummary/pdfContent. Accessed date: October 15, 2008.
89. Spitzer WO, Leblanc FE, Dupuis M. Scientific approach to the assessment and management of activity related spinal disorders. *Spine* 1987; 7:S1-59.
90. Cavanaugh JM, Lu Y, Chen C, Kallakuri S. Pain generation in lumbar and cervical facet joints. *J Bone Joint Surg Am* 2006; 88 Suppl 2:63-67.
91. Bogduk N. The clinical anatomy of the cervical dorsal rami. *Spine* 1982; 7:319-330.
92. Barnsley L, Bogduk N. Medial branch blocks are specific for the diagnosis of cervical zygapophyseal joint pain. *Reg Anesth* 1993; 18:343-350.
93. Zhang J, Tsuzuki N, Hirabayashi S, Saiki K, Fujita K. Surgical anatomy of the nerves and muscles in the posterior cervical spine. *Spine* 2003; 28:1379-1384.
94. Yin W, Bogduk N. The nature of neck pain in a private pain clinic in the United States. *Pain Med* 2008; 9:196-203.
95. Manchukonda R, Manchikanti KN, Cash KA, Pampati V, Manchikanti L. Facet joint pain in chronic spinal pain: An evaluation of prevalence and false-positive rate of diagnostic blocks. *J Spinal Disord Tech* 2007; 20:539-545.
96. Manchikanti L, Boswell MV, Singh V, Pampati V, Damron KS, Beyer CD. Prevalence of facet joint pain in chronic spinal pain of cervical, thoracic, and lumbar regions. *BMC Musculoskelet Disord* 2004; 5:15.
97. Manchikanti L, Singh V, Pampati V, Damron K, Beyer C, Barnhill R. Is there correlation of facet joint pain in lumbar and cervical spine? *Pain Physician* 2002; 5:365-371.
98. Manchikanti L, Singh V, Rivera J, Pampati, V. Prevalence of cervical facet joint pain in chronic neck pain. *Pain Physician* 2002; 5:243-249.
99. Speldewinde G, Bashford G, Davidson I. Diagnostic cervical zygapophyseal joint blocks for chronic cervical pain. *Med J Aust* 2001; 174:174-176.
100. Manchikanti L, Manchikanti K, Pampati V, Brandon D, Giordano J. The prevalence of facet joint-related chronic neck pain in postsurgical and non-postsurgical patients: A comparative evaluation. *Pain Pract* 2008; 8:5-10.
101. Lord SM, Barnsley L, Wallis BJ, Bogduk N. Chronic cervical zygapophysial joint pain with whiplash: A placebo-controlled prevalence study. *Spine* 1996; 21:1737-1744.
102. Barnsley L, Lord SM, Wallis BJ, Bogduk N. The prevalence of chronic cervical zygapophysial joint pain after whiplash. *Spine* 1995; 20:20-26.
103. Barnsley L, Lord S, Wallis B, Bogduk N. False-positive rates of cervical zygapophysial joint blocks. *Clin J Pain* 1993; 9:124-130.
104. Manchikanti L, Singh V, Falco FJ, Cash KA, Fellows B. Cervical medial branch blocks for chronic cervical facet joint pain: A randomized double-blind, controlled trial with one-year follow-up. *Spine (Phila Pa 1976)* 2008; 33:1813-1820.

105. 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.
106. Manchikanti L, Manchikanti KN, Damron KS, Pampati V. Effectiveness of cervical medial branch blocks in chronic neck pain: A prospective outcome study. *Pain Physician* 2004; 7:195-201.
107. Lord S, Barnsley L, Wallis B, McDonald G, Bogduk N. Percutaneous radio-frequency neurotomy for chronic cervical zygapophyseal-joint pain. *N Engl J Med* 1996; 335:1721-1726.
108. Sapir DA, Gorup JM. Radiofrequency medial branch neurotomy in litigant and non-litigant patients with cervical whiplash. *Spine* 2001; 26:E268-E273.
109. McDonald G, Lord S, Bogduk N. Long-term follow-up of patients treated with cervical radiofrequency neurotomy for chronic spinal pain. *Neurosurgery* 1999; 45:61-67.
110. Barnsley L. Percutaneous radiofrequency neurotomy for chronic neck pain: Outcomes in a series of consecutive patients. *Pain Med* 2005; 6:282-286.
111. Bogduk N. International Spinal Injection Society guidelines for the performance of spinal injection procedures. Part 1. Zygapophysial joint blocks. *Clin J Pain* 1997; 13:285-302.
112. Barnsley L, Lord S, Bogduk N. Comparative local anaesthetic blocks in the diagnosis of cervical zygapophysial joint pain. *Pain* 1993; 55:99-106.
113. Lord SM, Barnsley L, Bogduk N. The utility of comparative local anesthetic blocks versus placebo-controlled blocks for the diagnosis of cervical zygapophysial joint pain. *Clin J Pain* 1995; 11:208-213.
114. Manchikanti L, Cash KA, Pampati V, Fellows B. Influence of psychological variables on the diagnosis of facet joint involvement in chronic spinal pain. *Pain Physician* 2008; 11:145-160.
115. Manchikanti L, Manchikanti K, Cash KA, Singh V, Giordano J. Age-related prevalence of facet joint involvement in chronic neck and low back pain. *Pain Physician* 2008; 11:67-75.
116. Manchikanti L, Pampati V, Damron KS, McManus CD, Jackson SD, Barnhill RC, Martin JC. The effect of sedation on diagnostic validity of facet joint nerve blocks: An evaluation to assess similarities in population with involvement in cervical and lumbar regions. *Pain Physician* 2006; 9:47-52.
117. Manchikanti L, Pampati V, Damron KS, McManus CD, Jackson SD, Barnhill RC, Martin JC. A randomized, prospective, double-blind, placebo-controlled evaluation of the effect of sedation on diagnostic validity of cervical facet joint pain. *Pain Physician* 2004; 7:301-309.
118. Manchikanti KN, Manchikanti L, Damron KS, Pampati V, Fellows B. Increasing deaths from opioid analgesics in the United States: An evaluation in an interventional pain management practice. *J Opioid Manage* 2008; 4:271-283
119. Rubinstein SM, van Tulder M. A best-evidence review of diagnostic procedures for neck and low-back pain. *Best Pract Res Clin Rheumatol* 2008; 22:471-482.
120. 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.
121. 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.
122. 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.
123. 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.
124. 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.

125. Stolker RJ, Vervest AC, Groen GJ. Percutaneous facet denervation in chronic thoracic spinal pain. *Acta Neurochir* 1993; 122:82-90.
126. Dreyfuss P, Tibiletti C, Dreyer SJ. Thoracic zygapophyseal joint pain patterns: A study in normal volunteers. *Spine* 1994; 19:807-811.
127. Fukui S, Ohseto K, Shiotani M. Patterns of pain induced by distending the thoracic zygapophyseal joints. *Reg Anesth* 1997; 22:332-336.
128. Stolker RJ, Vervest AC, Groen GJ. Parameters in electrode positioning in thoracic percutaneous facet denervation: An anatomical study. *Acta Neurochir* 1994; 128:32-39.
129. Manchikanti L, Singh V, Pampati VS, Beyer CD, Damron KS. Evaluation of the prevalence of facet joint pain in chronic thoracic pain. *Pain Physician* 2002; 5:354-359.
130. 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.
131. Manchikanti L, Singh V, Falco FJE, Cash KA, Pampati V. Effectiveness of thoracic medial branch blocks in managing chronic pain: A preliminary report of a randomized, double-blind controlled trial; Clinical trial NCT00355706. *Pain Physician* 2008; 11:491-504.
132. Manchikanti L, Manchikanti KN, Manchukonda R, Pampati V, Cash KA. Evaluation of therapeutic thoracic medial branch block effectiveness in chronic thoracic pain: A prospective outcome study with minimum 1-year follow up. *Pain Physician* 2006; 9:97-105.
133. Bogduk N. Principles of diagnostic blocks. In: Slipman C, Derby R, Simeone FA, Mayer TG (eds). *Interventional Spine: An Algorithmic Approach*. Saunders Elsevier, Philadelphia, 2008, pp 187-192.
134. Bogduk N. Diagnostic nerve blocks in chronic pain. *Best Pract Res Clin Anaesthesiol* 2002; 16:565-578.
135. Manchikanti L, Singh V, Pampati V. Are diagnostic lumbar medial branch blocks valid? Results 2-year follow up. *Pain Physician* 2003; 6:147-153.
136. Manchikanti L, Pampati S, Cash KA. Making sense of accuracy of diagnostic lumbar facet joint nerve blocks: An assessment of implications of 50% relief, 80% relief, single block or controlled diagnostic blocks. *Pain Physician* 2010; 13:133-143.
137. Pampati S, Cash KA, Manchikanti L. Accuracy of diagnostic lumbar facet joint nerve blocks: A 2-year follow-up of 152 patients diagnosed with controlled diagnostic blocks. *Pain Physician* 2009; 12:855-866.
138. Saal JS. General principles of diagnostic testing as related to painful lumbar spine disorders. A critical appraisal of current diagnostic techniques. *Spine (Phila Pa 1976)* 2002; 27:2538-2545.
139. Manchikanti L, Damron KS, Rivera J, McManus C, Jackson S, Barnhill R, Martin J. Evaluation of effect of sedation as a confounding factor in the diagnostic validity of lumbar facet joint pain: A prospective, randomized, double-blind, placebo-controlled evaluation. *Pain Physician* 2004; 7:411-417.
140. Manchikanti L, Singh V, Fellows B, Pampati V. Evaluation of influence of gender, occupational injury, and smoking on chronic low back pain of facet joint origin: A subgroup analysis. *Pain Physician* 2002; 5:30-35.
141. Manchikanti L, Boswell MV, Manchukonda R, Cash KA, Giordano J. Influence of prior opioid exposure on diagnostic facet joint nerve blocks. *J Opioid Manage* 2008; 4:351-360.
142. Cavanaugh JM, Ozaktay AC, Yamashita T, Avramov A, Getchell TV, King AI. Mechanisms of low back pain: A neurophysiologic and neuroanatomic study. *Clin Orthop* 1997; 335:166-180.
143. Hirsch C, Ingelmark BE, Miller M. The anatomical basis for low back pain: Studies on the presence of sensory nerve endings in ligamentous, capsular and intervertebral disc structures in the human lumbar spine. *Acta Orthop Scand* 1963; 33:1-17.
144. McCall IW, Park WM, O'Brien JP. Induced pain referral from posterior lumbar elements in normal subjects. *Spine (Phila Pa 1976)* 1979; 4:441-446.

145. Fairbank JC, Park WM, McCall IW, O'Brien JP. Apophyseal injection of local anesthetic as a diagnostic aid in primary low-back pain syndromes. *Spine (Phila Pa 1976)* 1981; 6:598-605.
146. Marks R. Distribution of pain provoked from lumbar facet joints and related structures during diagnostic spinal infiltration. *Pain* 1989; 39:37-40.
147. Windsor RE, King FJ, Roman SJ, Tata N, Cone-Sullivan LA, Thampi S, Acebey M, Gilhool JJ, Rao R, Sugar R. Electrical stimulation induced lumbar medial branch referral patterns. *Pain Physician* 2002; 5:347-353.
148. 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; 12:541-560.
149. Manchikanti L, Pampati V, Fellows B, Pakanati RR. Prevalence of lumbar facet joint pain in chronic low back pain. *Pain Physician* 1999; 2:59-64.
150. Manchikanti L, Pampati V, Fellows B, Baha A. The inability of the clinical picture to characterize pain from facet joints. *Pain Physician* 2000; 3:158-166.
151. Manchikanti L, Hirsch JA, Pampati V. Chronic low back pain of facet (zygapophysial) joint origin: Is there a difference based on involvement of single or multiple spinal regions? *Pain Physician* 2003; 6:399-405.
152. Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. The relative contributions of the disc and zygapophyseal joint in chronic low back pain. *Spine (Phila Pa 1976)* 1994; 19:801-806.
153. Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. Clinical features of patients with pain stemming from the lumbar zygapophyseal joints. Is the lumbar facet syndrome a clinical entity? *Spine (Phila Pa 1976)* 1994; 10:1132-1137.
154. Schwarzer AC, Wang SC, Bogduk N, McNaught PJ, Laurent R. Prevalence and clinical features of lumbar zygapophysial joint pain: A study in an Australian population with chronic low back pain. *Ann Rheum Dis* 1995; 54:100-106.
155. Manchikanti L, Manchukonda R, Pampati V, Damron KS, McManus CD. Prevalence of facet joint pain in chronic low back pain in postsurgical patients by controlled comparative local anesthetic blocks. *Arch Phys Med Rehabil* 2007; 88:449-455.
156. Nath S, Nath CA, Pettersson K. Percutaneous lumbar zygapophysial (facet) joint neurotomy using radiofrequency current, in the management of chronic low back pain. A randomized double-blind trial. *Spine (Phila Pa 1976)* 2008; 33:1291-1297.
157. 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.
158. Dreyfuss P, Schwarzer AC, Lau P, Bogduk N. Specificity of lumbar medial branch and L5 dorsal ramus blocks. *Spine (Phila Pa 1976)* 1997; 22:895-902.
159. Kaplan M, Dreyfuss P, Halbrook B, Bogduk N. The ability of lumbar medial branch blocks to anesthetize the zygapophysial joint. *Spine (Phila Pa 1976)* 1998; 23:1847-1852.
160. Schwarzer AC, Derby R, Aprill CN, Fortin J, Kine G, Bogduk N. The value of the provocation response in lumbar zygapophysial joint injections. *Clin J Pain* 1994; 10:309-313.
161. Manchikanti L, Pampati V, Fellows B, Rivera J, Damron K, Beyer C, Cash K. Influence of psychological factors on the ability of diagnose chronic low back pain of facet joint origin. *Pain Physician* 2001; 4:349-357.
162. Manchikanti L, Singh V, Pampati V, Damron K, Barnhill R, Beyer C, Cash K. Evaluation of the relative contributions of various structures in chronic low back pain. *Pain Physician* 2001; 4:308-316.
163. West S, King V, Carey TS, Lohr KN, McKoy N, Sutton SF, Lux L. Systems to Rate the Strength of Scientific Evidence. Evidence Report/Technology Assessment No. 47. AHRQ Publication No. 02-E016. Rockville, MD: Agency for Healthcare Research and Quality, 2002.
164. Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow CD, Teutsch SM, Atkins D; Methods Work Group, Third US Preventive Services Task Force. Current methods of the US Preventive Services

- Task Force. *Am J Prevent Med* 2001; 20:21-35.
165. Manchikanti L, Pampati V, Bakhit CE, Rivera JJ, Beyer CD, Damron KS, Barnhill RC. Effectiveness of lumbar facet joint nerve blocks in chronic low back pain: A randomized clinical trial. *Pain Physician* 2001; 4:101-117.
 166. Manchikanti L, Singh V, Falco FJ, Cash KA, Pampati V. Lumbar facet joint nerve blocks in managing chronic facet joint pain: One-year follow-up of a randomized, double-blind controlled trial: Clinical Trial NCT00355914. *Pain Physician* 2008; 11:121-132.
 167. Nash TP. Facet joints - intra-articular steroids or nerve block? *Pain Clinic* 1989; 3:77-82.
 168. van Wijk RM, Geurts JW, Wynne HJ, Hammink E, Buskens E, Lousberg R, Knape JT, Groen GJ. Radiofrequency denervation of lumbar facet joints in the treatment of chronic low back pain: A randomized, double-blind, sham lesion-controlled trial. *Clin J Pain* 2005; 21:335-344.
 169. van Kleef M, Barendse GAM, Kessels A, Voets HM, Weber WE, de Lange S. Randomized trial of radiofrequency lumbar facet denervation for chronic low back pain. *Spine (Phila Pa 1976)* 1999; 24:1937-1942.
 170. Gallagher J, Petriccione Di Vadi PL, Wedley JR, Hamann W, Ryan P, Chikanza I, Kirkham B, Price R, Watson MS, Grahame R, Wood S. Radiofrequency facet joint denervation in the treatment of low back pain: A prospective controlled double-blind study to assess its efficacy. *Pain Clinic* 1994; 7:193-198.
 171. Leclaire R, Fortin L, Lambert R, Bergeron YM, Rossignol M. Radiofrequency facet joint denervation in the treatment of low back pain: A placebo-controlled clinical trial to assess efficacy. *Spine (Phila Pa 1976)* 2001; 26:1411-1416.
 172. Tekin I, Mirzai H, Ok G, Erbuyun K, Vatanserver D. A comparison of conventional and pulsed radiofrequency denervation in the treatment of chronic facet joint pain. *Clin J Pain* 2007; 23:524-529.
 173. Chou R, Huffman L. *Guideline for the Evaluation and Management of Low Back Pain: Evidence Review*. American Pain Society; Glenview, IL, 2009.
 174. Marks RC, Houston T, Thulbourne T. Facet joint injection and facet nerve block: A randomised comparison in 86 patients with chronic low back pain. *Pain* 1992; 49:325-328.
 175. Manchikanti L, Manchikanti K, Manchukonda R, Cash KA, Damron KS, Pampati V, McManus CD. Evaluation of lumbar facet joint nerve blocks in the management of chronic low back pain: A preliminary report of a randomized, double-blind controlled trial. Clinical Trial NCT000355914. *Pain Physician* 2007; 10:425-440.
 176. Bogduk N. Point of View. *Spine (Phila Pa 1976)* 2008; 33:1298.
 177. Freburger JK, Holmes GM, Agans RP, Jackman AM, Darter JD, Wallace AS, Castel LD, Kalsbeek WD, Carey TS. The rising prevalence of chronic low back pain. *Arch Intern Med* 2009; 169:3.
 178. 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.
 179. Manchikanti L, Gupta S, Benyamin R, Munglani R, Datta S, Hirsch JA, Ward SP. Critiquing the critiques: The American Pain Society guideline and the American Society of Interventional Pain Physicians' response to it. *Pain Physician* 2011; 14:E73-E80.
 180. Leclaire R, Bergeron Y, Lambert R, Rossignol M. In response to: Radiofrequency neurotomy for chronic lumbar facet pain – interpreting the evidence. *Pain Pract* 2010; 10:261-262.
 181. 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.
 182. Manchikanti L, Rivera J, Pampati V, Damron KS, McManus CD, Brandon DE, Wilson SR. One day lumbar epidural adhesiolysis and hypertonic saline neurolysis in treatment of chronic low back pain: A randomized double blind trial. *Pain Physician* 2004; 7:177-186.
 183. Heavner JE, Racz GB, Raj P. Percutaneous epidural neuroplasty. Prospective evaluation of 0.9% NaCl versus 10% NaCl with or without hyaluronidase. *Reg Anesth Pain Med* 1999; 24:202-207.

184. Veihelmann A, Devens C, Trouiller H, Birkenmaier C, Gerdesmeyer L, Refior HJ. Epidural neuroplasty versus physiotherapy to relieve pain in patients with sciatica: A prospective randomized blinded clinical trial. *J Orthop Science* 2006; 11:365-369.
185. Manchikanti L, Pampati V, Fellows B, Rivera JJ, Beyer CD, Damron KS. Role of one day epidural adhesiolysis in management of chronic low back pain: A randomized clinical trial. *Pain Physician* 2001; 4:153-166.
186. Manchikanti L, Pampati V, Bakhit CE, Pakanati RR. Non-endoscopic and endoscopic adhesiolysis in post lumbar laminectomy syndrome. A one-year outcome study and cost effective analysis. *Pain Physician* 1999; 2:52-58.
187. Manchikanti L, Pakanati R, Bakhit CE, Pampati V. Role of adhesiolysis and hypertonic saline neurolysis in management of low back pain. Evaluation of modification of Racz protocol. *Pain Digest* 1999; 9:91-96.
188. Gerdesmeyer L, Lampe R, Veihelmann A, Burgkart R, Gobel M, Gollwitzer H, Wagner K. Chronic radiculopathy. Use of minimally invasive percutaneous epidural neurolysis according to Racz. *Der Schmerz* 2005; 19:285-295.
189. Manchikanti L, Singh V, Cash KA, Pampati V, Datta S. A comparative effectiveness evaluation of percutaneous adhesiolysis and epidural steroid injections in managing lumbar post surgery syndrome: A randomized, equivalence controlled trial. *Pain Physician* 2009; 12:E355-E368.
190. Manchikanti L, Cash KA, McManus CD, Pampati V, Singh V, Benyamin RM. The preliminary results of a comparative effectiveness evaluation of adhesiolysis and caudal epidural injections in managing chronic low back pain secondary to spinal stenosis: A randomized, equivalence controlled trial. *Pain Physician* 2009; 12:E341-E354.