

American Society of Interventional Pain Physicians

" The Voice of Interventional Pain Management "

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Re: Minimally Invasive Treatment of Back Pain, Coverage Policy Number: 0139

Dr. Kang:

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. However, these medical policies have elicited significant confusion and the society has received multiple requests to comment and provide the evidence and also express the concern on the appropriateness of these policies and access to the insured population by CIGNA. The Executive Committee of ASIPP, on behalf of the ASIPP Board, and the entire membership, would like to provide comments for your medical policy bulletins. The primary objectives of these comments are to ensure that these procedures are provided appropriately and that patients insured by CIGNA 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).

It appears that you have given substantial weight for ACOEM guidelines (3,4) and NICE guidelines (5); however, both have been shown to be with significant deficiencies (5-8). Similar to these guidelines, APS also has published its own guidelines prepared by Chou and Huffman (9) published as multiple manuscripts (10,11), which are with substantial deficiencies and conflicts of interest (12-17). Similarly,

the guidelines prepared by societies may be considered conflicts of interest because they are benefiting from interventions (18,19). However, these conflicts are much less significant than conflicts derived from guidelines such as APS and ACOEM. In the same fashion, guidelines either sponsored or provided by insurers also have substantial conflicts. Finally, the evidence and guidelines provided by multiple organizations which essentially is becoming a cottage industry supported by tax dollars are also ridden with conflict as their total paycheck depends on the development of favorable guidelines for the sponsor.

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

1.0 EPIDURAL STEROID INJECTION/SELECTIVE NERVE ROOT BLOCK

The policy states:

CIGNA covers epidural steroid injection/selective nerve root block (CPT codes 62310, 62311, 64479-64484, 77003) as medically necessary for the treatment of acute or recurrent cervical, thoracic or lumbar radicular pain (e.g. sciatica) when improvement is not seen following at least three weeks of conservative management (e.g., pharmacological therapy, physical therapy, exercise).

CIGNA covers up to two subsequent epidural steroid injections/selective nerve root blocks block as medically necessary when there was at least three weeks of temporary, partial relief of symptoms following the prior injection, but radicular pain has persisted or worsened.

CIGNA does not cover long-term, repeated or maintenance epidural steroid injection /selective nerve root block for any indication because it is considered not medically necessary.

CIGNA does not cover EITHER of the following because each is considered experimental, investigational or unproven:

- Epidural steroid injection/selective nerve root block for acute, subacute, or chronic back pain
- Epidural steroid injection with ultrasound guidance (0231T, 0232T) for any indication

Thus, this policy covers only for radicular pain. It also covers 2 subsequent epidural steroid injections/selective nerve root blocks as medically necessary which is somewhat confusing.

Your policy does not cover long-term, repeated, or maintenance 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 Cigna 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). More recently 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.

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	120	77% vs. 80%	77% vs 82%	70% to 77%	<i>P</i>	<i>P</i>
Dashfield et al 2005 (31) *	RA, DB	Caudal = 30 Endoscopy = 30	SI	SI	NA	<i>P</i>	NA
Bush and Hillier 1991 (32)	RA, DB	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	C = 19 T = 16	20% vs 50%	20% vs 50%	NA	<i>P</i>	NA

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; P = prospective; C = control; T = treatment; NA = not available; SI = significant improvement; NSI = no 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).

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 (38). 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 (39). 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 (38,40)*	RA, DB	40	65% to 70%	60%	60% to 65%	P	P
Revel et al 1996 (41)	RA	Forceful injection = 29 Regular = 31	NA	49% vs 19%	NA	P	P
Hesla and Breivik 1979 (34)	RA, DB	69 patients: crossover design	77% vs 29%	59% vs 25%	59% vs 25%	P	P

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; 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.

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 (39,42)*	RA, DB	40	50% to 65%	60% to 65%	55% to 65%	P	P
Ciocon et al 1994 (43)	O	30	SI	SI	NA	P	NA
Botwin et al 2007 (44) *	O	34	65%	62%	54%	P	P

*Indicates use of fluoroscopy

RA = randomized; DB = double 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 (45,46)	RA, DB	64	78%	75% to 81%	72%	P	P
Manchikanti et al 2001(47)*	O	70	95%	85%	61% to 73%	P	P
Manchikanti et al 2002 (48) *	O	62	86%	60%	NA	P	NA

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; O = observational; 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, recently 2 systematic reviews were 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 is 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 being conducted with fluoroscopy which may change the results (49,50). Presently 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. The evidence was also negative for chronic low back pain of discogenic origin without radiculitis or disc herniation and no evidence is available in spinal stenosis. 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.

The recent systematic review of cervical epidural injections (23) also utilized blind cervical epidural studies with significant evidence as shown in Table 5. However, none of the studies were performed under fluoroscopy and such studies are awaiting publication.

Table 5. Results of randomized trials of effectiveness of cervical interlaminar epidural steroid injections.

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 (51)	RA, C	Group I - no steroid=35 Group II - steroid=35	77% vs. 86%	80% vs. 86%	80%	P	P
Manchikanti et al 2010 (52)	RA, C	Group I - no steroid=35 Group II - steroid=35	89% vs. 83%	77% vs. 74%	77% vs. 77%	P	P
Castagnera et al 1994 (53)	RA	Local anesthetic with steroids =14 Local anesthetic with steroids and morphine =10	79%	79%	79%	P	P
Stav et al 1993 (54)	RA	C = 17 T = 25	12% vs 68%	12% vs 68%	12% vs 68%	P	P
Pasqualucci et al 2007 (55)	RA	Single = 20 Continuous = 20 Over 180 days	NA	58% vs 74%	NA	P	NA

RA = randomized; C = control; 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 6 illustrates randomized trials of effectiveness of lumbar transforaminal epidural injections.

Table 6. 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 (56,57)	RA, DB	C = 80 T = 80	SICH	NSI	NSI	P	N
Riew et al 2000/ 2006 (58,59)	P, RA, DB	55	NA	NA	33% vs. 71% (avoided surgery)	P	P
Jeong et al 2007 (60)	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 (61)	RA	48	NA	NA	48% vs. 84%	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 (62,63) 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 only emerging for lumbar interlaminar epidural injections. Thus, you do not have to be concerned about using the same code for caudal epidural injections and lumbar interlaminar epidural injections. However, the codes are different for transforaminal epidural injections (49,50).

There is also emerging evidence for cervical epidural injections which appears to be fair even with old studies. Thus, permitting cervical epidural injections is also appropriate, specifically with emerging evidence (51,52). However, there is no significant evidence at the present time for thoracic epidural injections. Again, the same code is utilized for thoracic and cervical epidural injections (64).

There is only limited at the present time for thoracic epidural injections with only one study (64).

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. As your policy correctly says, they may not be covered for acute, subacute, or radicular pain or radicular syndromes.

CIGNA covers a diagnostic facet joint injection (CPT codes 64490-64495) as medically necessary when used to determine whether chronic neck or back pain is of facet joint origin when ALL of the following criteria are met:

- Pain is exacerbated by extension and rotation, or is associated with lumbar rigidity
- Pain has persisted despite appropriate conservative treatment (e.g., nonsteroidal anti-inflammatory drugs (NSAIDs), exercise)
- Clinical findings and imaging studies suggest no other obvious cause of the pain (e.g., spinal stenosis, disc degeneration or herniation, infection, tumor, fracture)

CIGNA does not cover therapeutic facet joint injection (CPT codes 64490-64495) for the treatment of acute, subacute, or chronic neck or back pain or radicular syndromes because it is considered experimental, investigational, or unproven.

CIGNA 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.

CIGNA 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:

- There is severe pain unresponsive to at least six months of conservative medical management. (e.g., pharmacological therapy, physical therapy, exercise).
- Facet joint origin of pain is suspected and medial branch block/injection of facet joint with local anesthetic results in elimination or marked decrease in intensity of pain.
- Clinical findings and imaging studies suggest no other obvious cause of the pain (e.g., spinal stenosis, disc degeneration or herniation, infection, tumor, fracture)

CIGNA 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 least six months have elapsed since the previous radiofrequency ablation/neurolysis of paravertebral facet joint nerves
- More than 50% relief is obtained , with associated functional improvement, for at least ten weeks following the previous treatment

CIGNA does not cover long-term, repeated or maintenance radiofrequency ablation/neurolysis of paravertebral facet joint nerves for any indication because it is considered not medically necessary.

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 (65-70). The diagnostic blocks applied in the precision diagnosis of chronic neck pain include cervical facet joint nerve blocks, and cervical provocation discography (65,67).

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 (71-74). Facet joints have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity (65,66,75-84). 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 (65,66,85-91).

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 (18,65,66,73). Construct validity of facet joint blocks is important to eliminate placebo effect as the source of confounding results and to secure true-positive results (18,65,66,75-84). 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 (18,65,66,92-94).

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 (81,95-99).

Based on the systematic review by Falco et al (65) diagnostic cervical facet joint nerve blocks, utilizing 9 studies (75-78,80-84) 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 (81).

Based on the systematic review by Falco et al (65), 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 7).

Table 7. 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 (83)	50	54% (95% CI, 40%, 68%).	NA
Barnsley et al 1993 (84)	55	NA	27% (95% CI, 15%, 38%)
Lord et al 1996 (82)	68	60% (95% CI, 46%, 73%)	NA
Manchikanti et al 2002 (78)	120	67% (95% CI, 58%, 75%)	63% (95% CI 48%, 78%)
Manchikanti et al 2004 (77)	255 of 500	55% (95% CI, 49%, 61%)	63% (95% CI 54%, 72%)
Manchukonda et al 2007 (76)	251 of 500	39% (95% CI, 32%, 45%)	45% (95% CI 37%, 52%)
Manchikanti et al 2008 (81)	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 (80)	97	36% (95% CI, 27%, 45%)	NA
Yin and Bogduk 2008 (75)	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 (65).

Further, Rubinstein and van Tulder (100), 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 (18,65,66,92,100-102), 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 (18,92,103-105). The diagnostic blocks applied in the precision diagnosis of chronic thoracic pain include thoracic facet joint nerve blocks, and thoracic provocation discography (18,92,103-105).

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 (18,92,103,104,106-109). Facet joints have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity (18,76,77,92,103,104,106-110). 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 (18,103,104,106,111-113).

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 (18,76,77,92,103,104,110). Construct validity of facet joint blocks is important to eliminate placebo effect as the source of confounding results and to secure true-positive results (18,76,77,92,103,104,110). 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 (18,92-94,103,104,114,115).

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 (116-119). 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 (97,98,120); and lack of influence of psychological factors on the validity of controlled thoracic diagnostic local anesthetic blocks of facet joints was demonstrated (95). Other variables including prior opioid exposure were also evaluated (96,121,122).

Based on the systematic review by Atluri et al (104) utilizing 3 studies (76,77,110), 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 8). 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 8).

Table 8. Data of prevalence with controlled diagnostic blocks and false-positive rates in thoracic region.

Study	Participants	Prevalence	False-Positive Rate
Manchikanti et al 2004 (76)	72	42% (95% CI 30%–53%)	55% (95% CI 39%–78%)
Manchukonda et al 2007 (77)	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 (112). Further, Rubinstein and van Tulder (100) 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 (18,103). The diagnostic blocks applied in the precision diagnosis of chronic low back pain include lumbar facet joint nerve blocks, lumbar provocation discography, and sacroiliac joint blocks (66,129,130).

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 (18,71,103,123-128). Facet joints have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity (18,66,76-78,92,103,129-137). 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 (18,66,103,138,139).

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 (18,66,92,103). Construct validity of facet joint blocks is important to eliminate placebo effect as the source of confounding results and to secure true-positive results (18,66,92,103,114). 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 (92-94,114,115).

The specificity of the effect of lumbar facet joint blocks was demonstrated in controlled trials (140,141). Provocation response of facet joint pain was shown to be unreliable in one study (142).

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 (116-118,142). 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 (97,120) and lack of influence of psychological factors on the validity of controlled lumbar diagnostic local anesthetic blocks of facet joints was demonstrated (95,143). Other variables including prior opioid exposure were also evaluated (96,121,122).

Based on the systematic review by Datta et al (66), 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 9). The overall prevalence is 31% (95% CI; 28%–33%).

Based on Datta et al's (66) 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 9).

Table 9. 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 (78)	120	40% (95% CI 31%–49%)	30% (95% CI 20%–40%)
Manchikanti et al 2004 (77)	397	31% (95% CI 27%–36%)	27% (95% CI 22%–32%)
Manchukonda et al 2007 (76)	303	27% (95% CI 22%–33%)	45% (95% CI 36%–53%)
Schwarzer et al 1995 # (136)	63	40% (95% CI 29%–53%)	NA
Manchikanti et al 2001 (144)	120	40% (95% CI 31%–49%)	47% (95% CI 35%–59%)
Manchikanti et al 2003 (133)	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 (137)	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 (142) 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 (145).

Evidence is Level I or II-1 based on the (USPSTF) criteria (146). Rubinstein and van Tulder (100) 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 (18,101-103) 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 10. 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 (147)	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 (139,148)	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 (138)	RA, DB	C = 20 * T = 20	NA	SI	SI	NA	P	NA
van Wijk et al 2005 (150)	RA, DB	C = 41 * T = 40	NA	39% versus 62%	NA	NA	P	NA
van Kleef et al 1999 (151)	RA, DB	C = 16 * T = 15	NA	25% vs 60%	19% vs 47%	13% vs 47%	P	N
Gallagher et al 1994 (152)	RA, DB	C = 12 * T = 18	SI = T	SI = T	SI = T	NA	P	NA
Leclaire et al 2001 (153)	RA, DB	C = 34 * T = 36	NSI	NSI	NA	NA	NA	NA
Tekin et al 2007 (154)	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 (102).

As of now, there are 2 randomized trials of facet joint nerve blocks have been published (139,147) meeting the methodological assessment criteria. However, Chou and Huffman (155) 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 (149,156). 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 (139,147) were shown to be of high quality even though one study (139,148) with 2 reports was not included in the analysis by Chou and Huffman (155), despite its publication prior to the search (157).

Manchikanti et al (148) 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 (139) 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 (138) was ideal and met the inclusion criteria by other evaluators (158). 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 (138). 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 (138) 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 (102,155,157,160,161).

Chou et al also included multiple studies which failed to meet inclusion criteria by others. These were by Gallagher et al (152), van Kleef et al (151), Leclaire et al (153), van Wijk et al (150), and Tekin et al (154). Surprisingly, the authors of these studies had conflicting opinions and Leclaire et al (153) have recanted their results and recommended the study must not be used for clinical purposes (162).

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 11. *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.	Long-term relief > 6 mos.
CERVICAL									
Manchikanti et al 2008 (85), 2010 (86)	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 (87)	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 (85,86) with one-year publication, and 2-year publication. There is also one prospective evaluation (87). Falco et al (65) reviewed the evidence from all the available medial branch blocks and included a randomized and observational study in their evaluation (87).

Manchikanti et al (85) 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 (86). 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 12. *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 (88)	RA, DB	24-control 24-active	♦ 1 of sham ♦ 7 of active	58% in active treatment group	P	P
Sapir and Gorup 2001 (89)	O	46	NA	Mean VAS change 4.6 ± 1.8	P	P
McDonald et al 1999 (90)	O	28	NA	71%	P	P
Barnsley 2005 (91)	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 (65).

With reference to radiofrequency neurotomy: for cervical radiofrequency neurotomy there was only one randomized trial which met inclusion criteria (88), and 3 observational studies (88-91).

In 1996, Lord et al (88) 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 (89) 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 (91) 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 (90), and similar to the one performed by Barnsley (91) 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 (146), 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 (86-88).

Table 13. 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 (111,112)	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 (113)	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 (146) the indicated level of evidence for thoracic facet nerve blocks is Level II-2 with a strong (1C) recommendation (18,103,104).

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 SACROILIAC JOINT (SI) JOINT INJECTION

Based on the policy, Cigna covers SI joint injections for the treatment of back pain associated with localized SI joint pathology (e.g., inflammatory arthritis) confirmed on imaging studies. Further, it also shows that inflammatory arthritis as it is shown in the literature there are no imaging findings to confirm SI joint pathology. Further, controlled diagnostic blocks appear to be the only means to evaluate sacroiliac joint pathology. We do agree that SI joint injections are not indicated for acute or subacute low back pain or for management of radicular syndromes.

CIGNA covers SI joint injection (CPT code 27096, HCPCS code G0260) for the treatment of back pain associated with localized SI joint pathology (e.g., inflammatory arthritis) confirmed on imaging studies.

CIGNA does not cover EITHER of the following because each is considered experimental, investigational, or unproven:

- SI joint injection (CPT code 27096) for the diagnosis or treatment of acute, subacute, or chronic back pain or radicular syndromes
- ultrasound guidance (76942) for SI joint injection for any indication

3.1 Diagnosis of Sacroiliac Joint Pain

In a systematic review evaluating a battery of tests to identify the disc, sacroiliac joint, or facet joint as the source of low back pain, Hancock et al (163) suggested that a combination of sacroiliac joint pain provocative maneuvers appears to be useful in pinpointing the sacroiliac joint as the principal source of symptoms in patients with pain below the fifth lumbar vertebra. They also concluded that although a positive bone scan has high specificity, it is associated with a very low sensitivity, which means that the majority of patients with the sacroiliac joint pain will not be accurately identified.

Rupert et al (129) presented the evidence with inclusion of 5 studies which met methodologic quality assessment. They estimated the prevalence of sacroiliac joint pain to range between 10% and 38% with 95% CI of 0% to 50%. As illustrated in Table 14, they also showed the false-positive rate of a single block to range between 20% and 54% with a 95% CI of 3% to 64%. Thus, they showed that the indicated evidence for the accuracy of sacroiliac joint diagnostic injections is Level II-2 for the diagnosis of sacroiliac joint pain in patients suspected of sacroiliac joint pain utilizing controlled diagnostic blocks.

The recommendations are as follows:

Controlled sacroiliac joint blocks with placebo or controlled comparative local anesthetic blocks are recommended when indications are satisfied. A positive response is considered $\geq 80\%$ relief with the ability to perform previously painful movements.

The primary indication for sacroiliac joint blocks is the need to know if a patient's pain is arising from the sacroiliac joint or not. Key indicators would be patients with chronic low back pain that is maximal below the level of L5 vertebra, with or without somatic referred pain in the lower limb, in whom no other diagnosis is readily apparent, in whom no other possible diagnosis is more likely, in whom a diagnosis has been made or cannot be made using less invasive options, whose pain is not evolving with the passage of time or conservative therapy, and fails to respond to conservative therapy.

Table 14. Data of prevalence of sacroiliac joint pain based on controlled diagnostic blocks.

Study	# of Subjects	Prevalence Estimates	False-Positive Rate
Manchikanti et al (164)	20	10% (95% CI; 0% - 23%)	22% (95% CI; 3% - 42%)
Maigne et al (1658)	54	18.5% (95% CI; 8% - 29%)	20% (95% CI; 8% - 33%)
Irwin e et al (166)	158	26.6% (95% CI; 20% - 34%)	53.8% (95% CI; 43% - 64%)
Laslett et al (167)	43/48	25.6% (95% CI; 12% - 39%)	0%
van der Wurff et al (168)	60	38% (95% CI; 26% - 51%)	21% (95% CI; 7% - 35%)

CI = confidence interval

Methodological criteria and scoring adapted from West S et al. *Systems to Rate the Strength of Scientific Evidence*, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. E016 (145).

Adapted from Rupert MP et al. Evaluation of sacroiliac joint interventions: A systematic appraisal of the literature. *Pain Physician* 2009; 12:399-418 (129).

3.2 Therapeutic Sacroiliac Joint Interventions

There is no significant evidence with regards to the therapeutic effectiveness of sacroiliac joint interventions as rightly showed in your evaluation and all other guidelines and systematic reviews. Rupert et al (129) in a systematic review provided the latest evidence with prevalence of sacroiliac joint pain to range between 10% and 38% with a false-positive rate of 20% to 54%. The evidence was Level II-3 or limited for therapeutic interventions with a weak recommendation.

Thus, these procedures may be approved with the same frequency limiting to a maximum of 4 therapeutic procedures per region – lumbar, with appropriate documentation if they meet indications and medical necessity as described above and the following indications utilizing appropriate frequency of interventions.

- ◆ Common indications are as follows:
 - Somatic or nonradicular low back and lower extremity pain below the level of L5 vertebra.
 - Duration of pain of at least 3 months.
 - Average pain levels of ≥ 6 on a scale of 0 to 10
 - Intermittent or continuous pain causing functional disability.
 - Failure to respond to more conservative management, including physical therapy modalities with exercises, chiropractic management, and non-steroidal anti-inflammatory agents.
 - Lack of obvious evidence for disc-related or facet joint pain.
 - No contraindications with understanding of consent, nature of the procedure, needle placement, or sedation.
 - No history of allergy to contrast administration, local anesthetics, steroids, Sarapin, or other drugs potentially utilized.

Recommendation for frequency of interventions are as follows:

- ◆ 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 would be 2 months or longer between injections, provided that > 50% relief is obtained for 2 months.
- ◆ If the procedures are done for different joints, they should be performed at intervals of no sooner than one week or preferably 2 weeks. It is suggested that therapeutic frequency remain at 2 months for each joint. It is further suggested that both joints be treated at the same time, provided the injections can be performed safely.
- ◆ In the treatment or therapeutic phase, the sacroiliac joint interventions should be repeated only as necessary according to the medical necessity criteria, and it is suggested that they be limited to a maximum of 4 times for local anesthetic and steroid blocks over a period of one year, per region.
- ◆ For sacroiliac joint radiofrequency neurotomy, the suggested frequency is 6 months or longer between each procedure (maximum of 2 times per year), provided that >50% relief is obtained for at least 3 to 4 months.

4.0 PERCUTANEOUS ADHESIOLYSIS

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

CIGNA 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 (169) utilizing 7 studies (170-176), 3 of which were randomized (170-172), 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 (177,178). In the study of post-lumbar surgery syndrome, Manchikanti et al (177) 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 (177)	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 (178)	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 (170)	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 (171)	RA, DB	59	49%	43%	49%	P	P
Veihelmann et al 2006 (172)	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 (169).

Spinal stenosis also has been studied in a randomized, double-blind, controlled trial (171). 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.



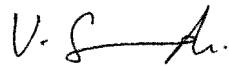
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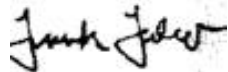
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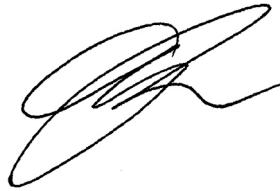
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