October 19, 2012

Matt Manders
President, Regional and Operations
Cigna Corporate Headquarters
900 Cottage Grove Road
Bloomfield, CT 06002

Re: Minimally Invasive Treatment of Back and Neck Pain
Effective Date: 7-15-2012
(Coverage Policy Number 0139)

Mr. Manders:

Thank you for publishing Cigna medical coverage policy effective date of 7-15-2012: Minimally Invasive Treatment of Back and Neck Pain (Coverage Policy Number 0139).

This letter is to present objections to your minimally invasive treatment of back and neck pain policy, along with providing appropriate literature.

On behalf of the American Society of Interventional Pain Physicians (ASIPP), we would like to thank you for the published guidelines. While we applaud the guidelines, the Executive Committee, on behalf of the ASIPP board and membership, would like to provide some of our views and also request you consider appropriately the evidence-based literature utilizing appropriate controlled design and critical analysis of the literature openly without bias.

Recently, the Institute of Medicine (IOM) has prepared guidance for the preparation of guidelines and systematic reviews (1,2). Cigna coverage policies seem to follow neither the guidance on the guidelines, nor on systematic reviews. There is absolutely no evidence that chronic pain is limited for one year and treatments are required for only one year. On the contrary, chronic pain is an ongoing issue. Chronicity has been shown to be present in the majority of the patients after initial episodes (3,4). Limiting treatment to one year is similar to limiting treatment for any chronic condition, such as diabetes, hypertension, or any other condition.

As illustrated below, well synthesized evidence utilizing the principles of IOM guidance (5-28) shows that caudal epidural injections, lumbar interlaminar epidural injections, lumbar transforaminal epidural injections, and cervical interlaminar epidural injections present with good evidence in managing disc herniation and radiculitis. However, the evidence seems to be fair in managing discogenic pain (after exclusion of facet joint pain), spinal stenosis, and post surgery syndrome. What is important is that these must be performed under fluoroscopic visualization utilizing contemporary interventional pain management modalities with appropriate outcome measures and repeat them as needed within certain limitations.

The evidence for diagnostic facet joint injections is good in the cervical, thoracic, and lumbar regions. Further, evidence for either radiofrequency neurotomy or therapeutic medial branch blocks is good when performed in contemporary interventional pain management practices with appropriate outcome measures, but with limitations.

The evidence for sacroiliac joint injections in the diagnosis of sacroiliac joint pain is good; however, the evidence for therapeutic modalities is only fair with cooled radiofrequency neurotomy. The evidence for therapeutic sacroiliac joint injections is emerging; thus, these should be permitted on a limited basis in contemporary interventional pain management settings.

The evidence for percutaneous adhesiolysis in spinal stenosis and post lumbar surgery syndrome is fair; thus, percutaneous adhesiolysis should be permitted after other conservative modalities have exhausted including epidural injections.

Introduction:
Interventional pain management is defined as the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment (29).

Interventional techniques are defined by MedPAC as minimally invasive procedures including, percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic diskectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain (30).

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 8,000 appropriately trained and qualified physicians practicing interventional pain management in the United States.

ASIPP is not only a not-for-profit organization, but also encompasses multiple components including regulatory, educational (evidence-based), and certification functions. ASIPP since its inception has continuously worked to reduce fraud and abuse, and provide education with well-designed didactic and cadaver workshops, standardization and certification in interventional pain management which is much more rigorous than any American Board of Medical Specialties (ABMS) certified examination with evaluation of technical competency for each and every individual physician, and competency certifications in controlled substance management and practice management. ASIPP has provided evidence-based guidelines since 2001 with revisions in 2003, 2005, 2007, and 2009, and awaiting publication of revision in 2012; multiple systematic reviews; and extensive evaluation of the literature. ASIPP also has performed critical analysis of multiple guidelines in the past along with multiple evidence-based manuscripts (5-28). While we are in the process of publishing our 2012 updated guidelines, we have published multiple systematic reviews (12-28).

Many of the components of ASIPP guidelines have been utilized by multiple Medicare carriers, including the National Government Services, CGS (formerly Cigna Government Services), Wisconsin Physician Services, Noridian, and many other carriers.

We would like to comment on minimally invasive treatment of back and neck pain with the hope that you will consider the present evidence and change the policies.

EPIDURAL STEROID INJECTION / SELECTIVE NERVE ROOT BLOCK

The policy states as follows:

Diagnostic Phase:

Cigna covers diagnostic epidural steroid injection/selective nerve root block (CPT codes 62310, 62311, 64479-64484) as medically necessary when BOTH of the following criteria are met:

- acute or recurrent cervical, thoracic or lumbar radicular pain (e.g. sciatica)
- failure to improve following at least six weeks of conservative management, including pharmacological therapy, physical therapy, and/or a home exercise program, OR worsening (e.g., incapacitating pain, advancing neurological symptoms) following at least two weeks of conservative management

A maximum of two diagnostic injection treatment sessions may be covered at a minimum interval of one week.

Therapeutic Phase

Cigna covers subsequent epidural steroid injections/selective nerve root blocks as medically necessary when prior diagnostic/stabilization injections resulted in a beneficial clinical response (e.g., improvement in pain, functioning, activity tolerance) and BOTH of the following criteria are met:

- cervical, thoracic or lumbar radicular pain (e.g., sciatica) has persisted or worsened
- injections are provided at a minimum frequency of two months

A maximum of four therapeutic injection treatment sessions may be covered for the same diagnosis/condition within a twelve month period, if preceding therapeutic injection resulted in more than 50% relief for at least six weeks.

Cigna does not cover long-term or maintenance epidural steroid injection /selective nerve root block (i.e., treatment for longer than twelve months) 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 without radiculopathy (e.g., sciatica)
- epidural steroid injection with ultrasound guidance (0228T-0231T) for any indication

This policy has multiple issues.

Diagnostic phase limitations are appropriate in reference to the number of procedures; however, indications are inappropriate. In the diagnostic phase, the procedures must be available for cervical spinal stenosis, thoracic spinal stenosis, and lumbar spinal stenosis with radicular pain and also without radicular pain after other diagnosis has been ruled out in reference to facet joint pain. Similarly, they should be available for axial or discogenic pain after facet joint pain has been excluded. Epidural injections have been shown to be effective in post surgery syndrome, spinal stenosis, as well as discogenic pain after ruling out the presence of facet joint pain (5,8,9,11-16).

The ASIPP guidelines and multiple systematic reviews of caudal epidural injections, lumbar interlaminar epidural injections, lumbar transforaminal epidural injections, cervical interlaminar epidural injections, and thoracic epidural injections showed variable evidence based on each condition (5,12-16). Overall, the evidence has been good to fair – superior compared to previous evaluations.

Caudal Epidural Injections

Parr et al (12) in a systematic review evaluated the effect of caudal epidural injections with or without steroids in managing various types of chronic low back pain with or without lower extremity pain emanating as a result of disc herniation or radiculitis, post lumbar laminectomy syndrome, spinal stenosis, and chronic discogenic pain.

They concluded that there was good evidence for short- and long-term relief of chronic pain secondary to disc herniation or radiculitis with local anesthetic and steroids and fair relief with local anesthetic only. Table 1 illustrates the studies utilized in managing lumbar disc herniation or radiculitis with caudal epidural injection (31-38).

In this evaluation, only randomized trials were included. Even though Iversen et al's study (31) was performed without fluoroscopy, it was included in this analysis considering that it would create much confusion and discussion by not including that study. Further, the study by Iversen et al (31) also included multiple flaws in their inclusion criteria and analysis, along with lack of fluoroscopy (10).

Table 1. *Results of randomized and observational studies of effectiveness of caudal epidural injections in managing disc herniation or radiculitis.*

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment(s)
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	1 year	
Iversen et al (31) R, PC, UL 6/12	Total = 116	Saline or triamcinolone acetonide with saline Number of injections = 2	N	N	N	U	U	U	Study has numerous deficiencies with flawed design.
Manchikanti et al (32,33) R, AC, F 10/12	Total = 120	Lidocaine vs. lidocaine mixed with steroid Number of injections = 1 to 5	77% vs. 80%	77% vs. 82%	70% vs. 77%	P	P	P	Positive double-blind randomized trial.
Ackerman & Ahmad (34) R, AC, F 7/12	Total = 90 Caudal = 30 Interlaminar = 30 Transforaminal = 30	methylprednisolone + saline Number of injections = 1 to 3	Caudal = 57% Interlaminar = 60% Transforaminal = 283%	Caudal = 57% Interlaminar = 60% Transforaminal = 83%	NA	P	P	NA	Relatively short-term follow-up with high volumes of injection.
Dashfield et al (35) R, AC, F 9/12	Total = 60 Caudal = 30 Endoscopy = 30	Lidocaine with triamcinolone Number of injections = 1	SI	SI	NA	P	P	NA	Positive in caudal group.
McCahon et al (36) R, AC, B 11/12	Total = 33	methylprednisolone vs. methylprednisolone with bupivacaine	SI in 40 mg group	NA	NA	P	NA	NA	Very small study.
Makki et al (37) R, AC, F 7/12	Total = 57	Position: supine vs side of leg pain	SI in lateral group	NA	NA	P	NA	NA	Small study.
Mendoza-Lattes et al (38) NR, RE, CC, F 6/10	Total = 93 Caudal = 39 Transforaminal = 54	Marcaine with depo-medrol Number of injections = 1 to 3	VAS 7.4 to 4.4 caudal group, trans-foraminal 7.9% to 5.7%	Surgery avoided in caudal group - 59%, in transforaminal epidural- 55.6%	Surgery avoided in caudal -59%, vs trans-foraminal - 55.6%	P	P	P	Approx. 60% of the patients improved.

R = Randomized; PC = Placebo Control; AC = Active Control; NR = Non-Randomized; RE = Retrospective; CC = Case Control; UL = Ultrasound; F = Fluoroscopy; B = Blind; P = Positive; N = Negative; NA = Not Applicable; U = Unclear; SI = Significant Improvement; ST = Steroid; LA = Local Anesthetic; SAL = Saline

Source: Parr AT, et al. Caudal epidural injections in the management of chronic low back pain: A systematic appraisal of the literature. *Pain Physician* 2012; 15:E159-E198 (12).

Parr et al (12) showed the evidence of randomized and observational studies in managing low back pain of post surgery syndrome as illustrated in Table 2 (39-42). Of these, 2 studies were performed under fluoroscopy. Further, this systematic review provided indicated evidence of fair for caudal epidural injections in managing post surgery syndrome.

Table 2. *Results of randomized trials of effectiveness of caudal epidural injections in managing post surgery syndrome.*

Study **Study Characteristics** **Methodological Quality Scoring**	**Participants**	**Interventions**	**Pain Relief and Function**			**Results**			**Comment(s)**
			3 mos.	**6 mos.**	**12 mos.**	**Short-Term ≤ 6 mos.**	**Long-Term**		
							> 6 mos	**≥ 1 year**	
Manchikanti et al (39,40) R, AC, F 11/12	Total = 140 Lidocaine = 70 Lidocaine + steroid = 70	lidocaine vs. lidocaine mixed with non particulate betamethasone Number of injections = 1 to 5	Pain relief 60% vs 69% Function 56% vs 57%	Pain relief 60% vs 66% Function 56% vs 63%	Pain relief 56% vs 61% Function 54% vs 61%	P	P	P	Positive results with local anesthetics with or without steroids.
Revel et al (41) R, AC, B 5/12	Total = 60	Prednisolone acetate and saline or prednisolone alone Number of injections = 6	NA	19% vs 45%	NA	NA	P	NA	Low quality study with positive results.
Yousef et al (42) R, AC, F 11/12	Total = 38 Local anesthetic = 18 Hypertonic saline = 20	Local anesthetic, steroids, hypertonic saline, and hyaluronidase Number of injections = 1	85% vs 80%	25% vs 75%	5% vs 45%	P	P	P	Significant improvement in hypertonic saline group.

R = Randomized; AC = Active Control; B = Blind; F = Fluoroscopy; P = Positive; N = Negative; NA = Not Applicable

Source: Parr AT, et al. Caudal epidural injections in the management of chronic low back pain: A systematic appraisal of the literature. *Pain Physician* 2012; 15:E159-E198 (12).

Parr et al (12) showed the evidence of randomized and observational studies in managing low back pain of spinal stenosis as illustrated in Table 3 (43-46). All of these studies were performed under fluoroscopy. This systematic review also provided indicated evidence of fair for caudal epidural injections in managing spinal stenosis

Table 3. *Results of randomized and observational studies of effectiveness of caudal epidural injections in managing spinal stenosis.*

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment(s)
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos	≥ 1 year	
Manchikanti et al (43,44) R, AC, F 11/12	Total = 100 Lidocaine = 50 Lidocaine + steroid = 50	Lidocaine 0.5% vs. lidocaine mixed with steroid. Number of injections = 1 to 5	66% vs. 62%	58% vs. 56%	48% vs. 46%	P	P	P	Double-blind design in a practical setting.
Barre et al (45) RE, F 7/13	Total = 95	triamcinolone and preservative free lidocaine Number of injections = 1 to 3	NA	NA	35%	NA	NA	N	Negative outcome study.
Lee et al (46) NR, RE, F 7/13	Total = 216	Local anesthetic and steroids. Number of injections = 1 to 16	86%	69%	46%	P	P	P	A large study with positive results.

R = Randomized; AC = Active Control; NR = Non-Randomized; RE = Retrospective; F = Fluoroscopy; P = Positive; N = Negative; NA = Not applicable

Source: Parr AT, et al. Caudal epidural injections in the management of chronic low back pain: A systematic appraisal of the literature. *Pain Physician* 2012; 15:E159-E198 (12).

Parr et al (12) showed the evidence of randomized trials and observational studies in managing low back pain of discogenic pain as illustrated in Table 4 (47-49). Both of these studies were performed under fluoroscopy. This systematic review also provided indicated evidence of fair for caudal epidural injections in managing chronic axial or discogenic pain.

Table 4. *Results of randomized and observational studies of effectiveness of caudal epidural injections in managing discogenic or axial pain with or without disc herniation or protrusion, without radiculitis, facet joint pain, or SI joint pain.*

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment(s)
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos	≥ 1 year	
Manchikanti et al (47,48) R, AC, F 10/12	Total = 120 Lidocaine = 60 Lidocaine with steroids = 60	Lidocaine vs. lidocaine mixed with steroid Number of injections = 1 to 5	87% vs. 88%	89% vs. 93%	84% vs. 85%	P	P	P	Positive randomized double-blind trial.
Southern et al (49) RE, F 7/13	Total = 97	Betamethasone and lidocaine Number of injections = 2 to 4	NA	NA	23%	NA	NA	N	A negative observational study.

R = Randomized; AC = Active Control; B = Blind; NR = Non-Randomized; RE = Retrospective; PR = Prospective; CC = Case Control; P = Positive; N = Negative; NA = Not Applicable; VAS = Visual Analog Scale; ODI = Oswestry Disability Index; SI = Sacroiliac; IL = Interlaminar; TF = Transforaminal

Source: Parr AT, et al. Caudal epidural injections in the management of chronic low back pain: A systematic appraisal of the literature. *Pain Physician* 2012; 15:E159-E198 (12).

Lumbar Interlaminar Epidural Injections

Lumbar interlaminar epidural injections have been studied for disc herniation, spinal stenosis, and discogenic pain (13). The results were evaluated appropriately utilizing methodologic quality assessment criteria of randomized and observational studies.

Benyamin et al (13) in a systematic review evaluated the effect of lumbar interlaminar 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, spinal stenosis, and chronic discogenic pain. They concluded that the evidence based on this systematic review is good for lumbar epidural injections under fluoroscopy for radiculitis secondary to disc herniation with local anesthetic and steroids.

Table 5 shows the effectiveness of lumbar interlaminar epidural injections in managing disc herniation and radiculitis (34,50-68). Of the 19 randomized trials, 9 were performed under fluoroscopy (34,50-56,61).

Table 5. *Results of randomized studies of effectiveness of lumbar interlaminar epidural injections in managing disc herniation or radiculitis.*

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	1 year	
Manchikanti et al (50,51) R, AC, F 10/12	Total = 120 Local anesthetic = 60 Local anesthetic and steroids = 60	Xylocaine or Xylocaine with non-particulate Celestone Number of injections = 1 to 5	72% vs. 82%	63% vs. 85%	67% vs. 85% or 80% vs. 86% in successful group	P	P	P	Positive randomized trial.
Lee et al (52) R, AC, F 7/12	Total = 93 IL = 34 TF = 59	Lidocaine with triamcinolone Number of injections = 1 to 3	SI in both groups	SI in both groups	SI in both groups	P	NA	NA	Positive randomized trial.
Rados et al (53) R, AC, F 8/12	Total = 64 IL = 32 TF = 32	Lidocaine with methylprednisolone Number of injections = 1 to 3	53% vs. 63%	53% vs. 63%	NA	P	P	NA	Short follow-up period.
Buttermann (54) R, AC, F 4/12	Total = 169 Epidural = 38 Discectomy = 119	Local anesthetic and steroids Number of injections = 1	U	U	U	U	U	U	Small, low-quality study.
Kim & Brown (55) R, AC, F 9/12	Total = 60 Depo-Medrol = 30 Dexamethasone = 30	Methylprednisolone or dexamethasone with bupivacaine Number of injections = 1 to 2	NA	NA	U	NA	NA	NA	Relatively small study, with active-control design.
Amr (56) R, AC, F 10/12	Total = 200 Steroid = 100 Steroid + Ketamine = 100	Triamcinolone plus preservative free ketamine and 0.9% saline Number of injections = 1	SI in ketamine group	SI in ketamine group	SI in ketamine group	N = steroids P = local anesthetic*	N = steroids P = local anesthetic	N = steroids P = local anesthetic	Significant improvement in both groups, with steroids with or without ketamine.
Buchner et al (57) R, B, AC 7/12	Total = 36 Methylprednisolone group = 17 Control group = 19	Rehabilitation program vs. epidural injections with methylprednisolone and bupivacaine Number of injections = 3 in 14 days	P	P	NA	P = steroids N = local anesthetic	P = steroids N = local anesthetic	NA	A small study comparing rehabilitation to epidural injections.
McGregor et al (58) R, B, AC 5/12	Total = 44 Caudal = 22 Lumbar = 22	Bupivacaine with hydrocortisone in saline Number of injections = 1	NSI	NSI	NA	N	N	NA	Low quality study in a small number of patients without fluoroscopy.
Dilke et al (59) R, B, PC 8/12	Total = 100 Epidural = 50 Interspinous = 50	Methylprednisolone in normal saline or interspinous ligament Number of injections = 1-2	P	NA	NA	P	NA	NA	Placebo control trial with positive responses.
Rogers et al (60) R, B, AC 10/12	Total = 30 Steroid epidural = 15 Non-steroid epidural = 15	Lignocaine with or without methylprednisolone Number of injections = 1	P	NA	NA	P	NA	NA	A small prospective single blind study.

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	1 year	
Candido et al (61) R, AC, F 7/12	Total = 57 Parasagittal interlaminar = 29 Transforaminal = 28	Number of injections = 1-3	NA	NA	NA	NA	NA	NA	Small study.
Ackerman & Ahmad (34) R, AC, F 7/12	Total = 90 Caudal = 30 Interlaminar = 30 Transforaminal = 30	Steroid and saline with local anesthetic. Number of injections = 1 to 3	P	P	NA	P	P	NA	Positive results.
Kraemer et al (62) R, B, PC, AC 7/12	Total = 133 Perineal = 47 Epidural = 40 Intramuscular = 46	Triamcinolone and local anesthetic Number of injections = 3	68% vs. 53.3% vs. 34.8%	NA	NA	P	NA	NA	Positive results.
Pirbudak et al (63) R, B, AC 10/12	Total = 92 Epidural = 46 Epidural + amitriptyline = 46	Betamethasone and bupivacaine or with addition of amitriptyline Number of injections = 1 to 3	SI in both groups	SI in both groups	SI in both groups	P = steroids P = local anesthetic**	P = steroids P = local anesthetic**	P = steroids P = local anesthetic**	Active control trial with positive results.
Arden et al (64) R, B, PC 11/12	Total = 228 Steroid group = 120 Placebo group = 108	Triamcinolone and bupivacaine or normal saline into interspinous ligament Number of injections = 3	NSI	NSI	NSI	N	N	N	Negative results with transient relief in steroid group with multiple deficiencies.
Carette et al (65) R, B, PC 11/12	Total = 158 Methylprednisolone = 78 Placebo 80	Normal saline vs. depo methylprednisolone and procaine Number of injections = 1 to 3	NSI	NSI	NSI	N	N	N	Inappropriate blind placebo trial with negative results.
Cuckler et al (66) R, B, AC 8/12	Total = 36 Steroid group = 22 Local anesthetic group = 14	Procaine or methylprednisolone acetate combined with procaine Number of injections = 1 to 2	NSI	NSI	NSI	N	N	N	A small study without fluoroscopy in acute disc herniation.
Wilson-MacDonald et al (67) R, B, AC 10/12	Total = 60 Intramuscular = 34 Epidural = 26	Intramuscular injection or epidural bupivacaine with methylprednisolone Number of injections = 1 to 2	SI in the treatment group	U	U	P	U	U	Small study.
Ridley et al (68) R, B, PC 9/12	Total = 35 Active group = 19 Placebo group = 16	Interspinous saline vs. epidural methylprednisolone and physiological saline Number of injections = 1	SI	U	U	P	U	U	A small study without injection of local anesthetic.

* = Ketamine group; ** = Amitriptyline; R = Randomized; PC = Placebo Control; AC = Active Control; F = Fluoroscopy; B = Blind; IL = Interlaminar; TF = Transforaminal; ST = Steroid; LA = Local Anesthetic; SAL = Saline; SI = Significant Improvement; NSI – No Significant Improvement; P = Positive; N = Negative; NA = Not Applicable; U = Unclear

Source: Benyamin RM, et al. The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. *Pain Physician* 2012; 15:E363-E404 (13).

Benyamin et al (13) in their systematic review of lumbar interlaminar epidurals concluded that there was fair evidence for management of spinal stenosis with lumbar interlaminar epidural injections. Table 6 shows the effectiveness of lumbar interlaminar epidural injections in managing in spinal stenosis based on randomized trials (52,66,67,69-71). There was only one observational report (72). Of these, 3 trials were performed under fluoroscopy (52,69,70).

Table 6. *Results of randomized trials of effectiveness of lumbar interlaminar epidural injections in managing spinal stenosis.*

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comments
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-TERM > 6 mos.	Long-TERM ≥ 1 year	
Manchikanti et al (69) R, AC, F 10/12	Total = 60 Local anesthetic = 30 Local anesthetic and steroids = 30	Local anesthetic or local anesthetic with non-particulate Celestone. Number of injections = 1 to 5	77% vs. 63%	67% vs. 67%	70% vs. 60%	P	P	P	The first randomized controlled study with long-term follow-up.
Lee et al (52) R, AC, F 7/12	Total = 99 IL = 42 Bilateral TF = 57	Lidocaine and triamcinolone Number of injections = 1 to 3	SI in both groups	NA	NA	P	NA	NA	Short-term follow-up.
Koc et al (70) R, AC, F 5/12	Total = 29 Inpatient physical therapy = 10 Epidural steroid injection = 10 No treatment = 9	Physical therapy program or epidural injection triamcinolone and bupivacaine Number of injections = 1	SI in both groups vs. control	SI in both groups vs. control	NA	P	P	NA	A very small study with positive results.
Fukasaki et al (71) R, B, AC, PC 9/12	Total = 53 Epidural saline = 16 Mepivacaine = 18 Mepivacaine and methylprednisolone = 19	Saline or mepivacaine ora combination of mepivacaine and methylprednisolone Number of injections = 1-3	12.5% vs. 55.5% vs. 63.2%	NA	NA	P = steroids & local anesthetics N = saline	NA	NA	A small study with 3 groups.
Cuckler et al (66) R, B, AC 8/12	Total = 37 Steroid group = 20 Local anesthetic group = 17	Procaine with or without methylprednisolone Number of injections = 1 to 2	NSI	NSI	NSI	N	N	N	A small study without fluoroscopy.
Wilson-MacDonald et al (67) R, B, AC 10/12	Total = 50 Epidural = 21 Intramuscular injection (control) = 29	Intramuscular injection in the epidural area or epidural with bupivacaine or methylprednisolone Number of injections = 1	SI in treatment group	U	U	P	U	U	A small study without fluoroscopy.

R = Randomized; AC = Active Control; PC = Placebo Controlled; B = Blind; F = Fluoroscopy; ST = Steroid; LA = Local Anesthetic; SAL = Saline; P = Positive; N = Negative; NA = Not applicable; U = Unclear; SI = Significant improvement; NSI = No Significant Improvement

Source: Benyamin RM, et al. The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. *Pain Physician* 2012; 15:E363-E404 (13).

Benyamin et al (13) in their systematic review of lumbar interlaminar epidurals concluded that there was fair evidence for management of discogenic pain with lumbar interlaminar epidural injections. Table 7 shows the effectiveness of lumbar interlaminar epidural injections in managing in discogenic pain (73-75). All of the included studies were performed under fluoroscopy (73-76).

Table 7. *Results of randomized and observational studies of effectiveness of lumbar interlaminar epidural injections in managing discogenic or axial pain without disc herniation, radiculitis, facet joint pain or SI joint pain.*

Study **Study Characteristics** **Methodological Quality Scoring**	**Participants**	**Interventions**	**Pain Relief and Function**			**Results**			**Comments**
						Short-Term ≤ 6 mos.	**Long-Term**		
			3 mos.	**6 mos.**	**12 mos.**		**> 6 mos.**	**≥ 1 year**	
Manchikanti et al (73,74) R, AC, F 10/12	Total = 120 Local anesthetics = 60 Local anesthetics and steroids = 60	Lidocaine alone or with Celestone Number of injections = 1 to 5	83% vs. 73%	72% vs. 75%	77% vs. 67%	P	P	P	Positive results in a large active control trial.
Buttermann (75) NR, F 7/13	Epidural patients = not known	Betamethasone Number of injections = 1-2	U	U	U	U	U	U	Confusing design with inaccurate therapy.
Lee et al (76) NR, F 6/13	Total = 81	Triamcinolone with saline and bupivacaine Number of injections = 1 to 3	78%	77.5%	U	P	P	U	Positive results in an observational report.

P = Positive; U = Unclear

Source: Benyamin RM, et al. The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. *Pain Physician* 2012; 15:E363-E404 (13).

Lumbar Transforaminal Epidural Injections

Manchikanti et al (14) in a systematic review evaluated the effect of therapeutic transforaminal lumbar epidural steroid injections in managing low back and lower extremity pain. They concluded that the evidence is good for radiculitis secondary to disc herniation with local anesthetics and steroids and fair with local anesthetic only. Table 8 illustrates the effectiveness of lumbar transforaminal epidural injections in managing disc herniation or radiculitis demonstrated in randomized trials (34,52,53,61,77-88). Non-randomized evaluations were not included (38,89-94).

Table 8. *Results of randomized and observational studies of effectiveness of transforaminal epidural injections in managing disc herniation or radiculitis.*

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment(s)
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	1 year	
Ghahreman et al (77) R, PC 12/12	Total = 150 5 groups with 28, 37, 27, 28, 30	Steroids with saline vs local anesthetic vs Intramuscular steroids vs Intramuscular saline Number of injections = 1 to 3	Transforaminal saline = 19% Transforaminal local anesthetic = 7% Transforaminal epidural = 54%	NA	NA	P = steroids N= local anesthetic & saline	N	NA	This study was the first of its nature with a true placebo evaluation.
Karppinen et al (78,79) R, PC 11/12	Total = 160 Methylprednisolone-bupivacaine = 80 Saline = 80	Sodium chloride solution, or methylprednisolone (40 mg) and bupivacaine (5 mg) Number of injections = 1	NA	SI in both groups	SI in both groups	U	U	U	An ineffective or inappropriate placebo technique.
Jeong et al (80) R, AC 9/12	Total = 193 Ganglionic (G) = 104 Preganglionic (PG) = 89	0.5 mL of bupivacaine hydrochloride and 40 mg of 1 mL of triamcinolone Number of injections = 1	PG = 88.4% G = 70.9%	PG = 60.4% G = 67.2%	NA	P	P	NA	Multiple deficiencies noted in the quality assessment.
Gerszten et al (81) R, AC 7/12	Total = 90 PDD = 46 TF = 44	Plasma disc decompression or transforaminal Number of injections = 2	NA	VAS and ODI 21% and PDD - 49%, versus 32% and 15%	VAS and ODI - 18% PDD - 44%, vs 25%, and 10%	U	N	N	The study evaluated 2 dissimilar modalities of treatments.
Riew et al (82,83) R, AC 8/12	Total = 55 Bupivacaine = 27 Bupivacaine + steroid = 28	Bupivacaine 0.25% or bupivacaine with 6 mg of betamethasone Number of injections = 1 to 4	NA	NA	33% vs 71% (avoided surgery)	P = steroids Unsure = local anesthetic	P = steroids Unsure = local anesthetic	P = steroids Negative = local anesthetic	Surgery was avoided in 33% of bupivacaine group and 71% in the steroid group.
Vad et al (84) R, AC 5/12	Total = 48 Trigger point injections = 23 Transforaminal epidural=25	Trigger point injections or transforaminal epidural Number of injections = 1 to 3	NA	NA	Roland-Morris Disability Scores 48% vs 84%	NA	NA	P	The study was not blinded.
Ng et al (85) R, AC 11/12	Total = 49 Bupivacaine = 26 Bupivacaine + steroid = 23	Bupivacaine only, or bupivacaine with methylprednisolone. Number of injections = 1	Bupivacaine = 47.5% Bupivacaine + steroid = 41.5%	NA	NA	P = steroids Negative = local anesthetic	NA	NA	Small study and short-term follow-up.

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment(s)
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	1 year	
Lee et al (52) R, AC 7/12	Total = 93 IL = 34 TF = 59	Interlaminar vs transforaminal epidural injections. 4 mL (TF) Number of injections = 1 to 3	Roland Pain Score Transforaminal = 3.34 to 1.59 Interlaminar = 3.25 to 1.57	NA	NA	P	NA	NA	Short-term study.
Ackerman & Ahmad (34) R, AC 7/12	Total = 90 Caudal = 30 Interlaminar = 30 Transforaminal = 30	Steroid and saline with local anesthetic Number of injections = 1 to 3	Caudal = 57% Interlaminar =l 60% Transforaminal = 83%	Caudal = 57%) Interlaminar = 60% Transforaminal = 83%	NA	P	P	NA	Relatively short-term follow-up with high volumes of injection.
Candido et al (61) R, AC 7/12	Total = 60 TF = 30 PIL = 30	Lateral parasagittal interlaminar epidural or transforaminal epidural Number of injections = 1 to 3	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	NA	Focus on the contrast medium spread and the related relief.
Park et al (86) R, AC 7/12	Total = 106 Dexamethasone = 53 Triamcinolone acetate = 53	Dexamethasone or triamcinolone acetate with lidocaine. Number of injections = 1	Dexamethasone = 40% Triamcinolone = 71%.	NA	NA	P**	NA	NA	Triamcinolone was more effective than dexamethasone.
Burgher et al (87) R, AC 12/12	Total = 26 Clonidine = 11 Triamcinolone = 15	Lidocaine with clonidine, or 4 triamcinolone Number of injections = 1 to 3	SI in both groups	NA	NA	U	NA	NA	Small study.
Rados et al (53) R, AC 8/12	Total=64 IL = 32 TF = 32	Interlaminar vs transforaminal Number of injections = 1 to 3	TF = 53% IL = 75%	TF = 53% IL = 75%	NA	P	P	NA	Short-term follow-up period.
Tafazal et al (88) R, AC 10/12	Total = 76 Bupivacaine = 34 Bupivacaine + steroid = 42	Bupivacaine with methylprednisolone Number of injections = 1 to 3	VAS and ODI change Bupivacaine = 24.3 and 13.8 Bupivacaine + steroid = 27.4 and 13.6	P	NA	P	P	P	No differences.

R = Randomized; PC = Placebo Control; AC = Active Control; IL = Interlaminar TF = Transforaminal; NSCH = No Significant Change; P = Positive; N = Negative; NA = Not Applicable; U = Unclear; G = Ganglionic; PG = Preganglionic; PDD = Plasma Disc Decompression; PIL = Parasagittal Interlaminar; ST = Steroid; LA = Local Anesthetic; SAL = Saline; VAS = Visual Analog Scale; ODI = Oswestry Disability Index; CT = Computed Tomography; ** = Triamcinolone Compared Dexamethasone

Source: Manchikanti L, et al. Effectiveness of therapeutic lumbar transforaminal epidural steroid injections in managing lumbar spinal pain. *Pain Physician* 2012; 15:E199-E245 (14).

Manchikanti et al (14) in a systematic review evaluated the effect of therapeutic transforaminal lumbar epidural steroid injections in managing low back and lower extremity pain. They concluded that the evidence is fair for radiculitis secondary to spinal stenosis with local anesthetic and steroids. Table 9 illustrates the effectiveness of lumbar transforaminal epidural injections in managing spinal stenosis (52,80,85,88,89,91,92,95,96).

Table 9. *Results of randomized and observational studies of effectiveness of transforaminal epidural injections in managing spinal stenosis.*

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment (s)
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos	≥ 1 year	
Jeong et al (80) R, AC 9/12	Total = 46 Ganglionic = 23 Preganglionic = 23	Bupivacaine with triamcinolone Number of injections = 1	89.1%	56.5%	NA	P	P	NA	Multiple deficiencies noted in the quality assessment.
Ng et al (85) R, AC 11/12	Total = 32 Bupivacaine = 15 Bupivacaine + steroid = 17	Bupivacaine only, or bupivacaine with methylprednisolone. Number of injections = 1-2	Pain and ODI Bupivacaine = 47.5% and 41.5%	NA	NA	P	NA	NA	A small number of patients with short follow-up period.
Lee et al (52) R, AC 7/12	Total = 99 IL = 42 Bilateral TF = 57	Lidocaine with triamcinolone Number of injections = 1 to 3	Transforaminal = 3.34 to 1.59 Interlaminar = 3.25 to 1.57	NA	NA	P	NA	NA	Bilateral transforaminal epidural steroid injections were superior.
Tafazal et al (88) R, AC 10/12	Total = 48 Bupivacaine = 25 Bupivacaine + steroid = 23	Bupivacaine or bupivacaine with methylprednisolone Number of injections = 1 to 3	VAS and ODI change Bupivacaine = 20.4 and 6.5 Bupivacaine + steroid = 19.4 and = 1.5	NA	NA	N	N	N	Disc herniation showed superior results.
Park & Lee (95) NR, PR 5/13	Total = 55	Triamcinolone and lidocaine Number of injections = 1	Significant improvement	NA	NA	P	NA	NA	No prognostic usefulness of high sensitivity C-reactive protein.
Lee et al (91) NR, RE 6/10	Total = 138 Interlaminar = 33 Caudal = 40 Transforaminal = 49	Lidocaine with triamcinolone Number of injections = 1	Transforaminal = 53% Interlaminar = 57.6% Caudal = 30%	NA	NA	P	NA	NA	Transforaminal was superior to caudal; however, equal to interlaminar.
Cooper et al (96) NR, RE, CC 6/13	Total = 61	Triamcinolone with lidocaine	44.2%	NA	37.2%	P	NA	N	Negative study.
Rosenberg et al (92) NR, RE 6/13	Total = 26	methylprednisolone with 1 mL of 1.5% lidocaine with epinephrine Number of injections = 1 to 4	54%	19%	35%	P	N	N	Small study with only 26 patients with spinal stenosis.
Ng & Sell (89) NR, P, RE 7/13	Total = 62	Bupivacaine and methylprednisolone. Number of injections = Unclear	Mean change of VAS of 1.2, ODI change of at least 10% in 37%.	NA	NA	N	NA	NA	Negative study.

R = Randomized; AC = Active Control; NR = Non-Randomized; RE = Retrospective; PR = Prospective; CC = Case-Control; P = Positive; N = Negative; NA = Not Applicable; VAS = Visual Analog Scale; ODI = Oswestry Disability Index; IL = Interlaminar; TF = Transforaminal

Source: Manchikanti L, et al. Effectiveness of therapeutic lumbar transforaminal epidural steroid injections in managing lumbar spinal pain. *Pain Physician* 2012; 15:E199-E245 (14).

Cervical Epidural Injections

Cervical epidural injections also have been studied in multiple studies and a systematic review has been performed recently (15). There have been condition specific evaluations of cervical epidural injections. Table 10 illustrates the effectiveness of cervical interlaminar epidural injections in disc herniation and radiculitis (97-105).

Diwan et al (15) in a systematic review evaluated the effect of cervical interlaminar epidural injections in managing various types of chronic neck and upper extremity pain emanating as a result of cervical spine pathology. They concluded that the evidence is good for radiculitis secondary to disc herniation with local anesthetics and steroids, fair with local anesthetic only; whereas, it is fair for local anesthetics with or without steroids, for axial or discogenic pain, pain of central spinal stenosis, and pain of post surgery syndrome.

Table 10. *Results of randomized trials of effectiveness of cervical interlaminar epidural injections.*

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment(s)
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term > 6 mos.	Long-Term 1 year	
DISC HERNIATION AND RADICULITIS									
Manchikanti et al (97,98) R, AC, F 11/12	120 local anesthetic = 60 Local anesthetic with steroids = 60	Local anesthetic or with Celestone Number of injections = 1 to 4	83% vs. 70%	82% vs. 73%	72% vs. 68%	P	P	P	Positive large study.
Castagnera et al (99) R, AC, B 7/12	24	local anesthetic with steroid or steroid plus morphine Number of injections = 1	79.2%	79.2%	79.2%	P	P = steroids N = local anesthetics	P	A small study with positive results.
Stav et al (100) R, AC, B 7/12	42	local anesthetic with steroid or IM steroid Number of injections = 1 to 3	NA	NA	68% vs.11.8%	NA	NA	P	A small study showing satisfactory improvement.
Pasqualucci et al (101) R, AC, B 7/12	40 of 160	Bupivacaine with methylprednisolone acetate	NA	Single vs. continuous 58.5%, 73.7% improvement	NA	NA	P	NA	Small study with positive results.
DISCOGENIC PAIN									
Manchikanti et al (102,103) R, AC, F 10/12	120	Local anesthetic or with Celestone	68% vs. 77%	67% vs. 73%	72% vs. 68%	P	P	P	Positive results.
SPINAL STENOSIS									
Manchikanti et al (104) R, AC, F 10/12	60	Local anesthetic or with Celestone	77% vs. 87%	87% vs. 80%	73% vs. 70%	P	P	P	Positive results.

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment(s)
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	1 year	
POST SURGERY SYNDROME									
Manchikanti et al (105) R, AC, F 10/12	56	Local anesthetic or with Celestone	68% vs. 68%	64% vs. 71%	71% vs. 64%	P	P	P	Positive results.

R = Randomized; AC = Active-Control; F = Fluoroscopy; B=Blind; VAS = Visual Analog Scale; P = positive; N = negative; NA = not applicable

Source: Diwan SA, et al. Effectiveness of cervical epidural injections in the management of chronic neck and upper extremity pain. *Pain Physician* 2012; 15:E405-E434 (15).

Thoracic Interlaminar Epidural Injections

The evidence for thoracic interlaminar epidural injections was determined in only one study. Based on this study, the evidence was judged to be fair.

Benyamin et al (16) in a systematic review evaluated the effects of thoracic interlaminar epidural injections with or without steroids, with or without fluoroscopy, and for various conditions including disc herniation and radiculitis, axial or discogenic pain, spinal stenosis, post thoracic surgery syndrome, and post thoracotomy pain syndrome. They concluded that the evidence for thoracic epidural injection in treating chronic thoracic pain is considered fair and limited for post thoracotomy pain.

Table 11 illustrates the studies utilized in the evaluation of thoracic interlaminar epidural injections (106,107).

Table 11. *Assessment of randomized trials and non-randomized studies for inclusion criteria.*

Manuscript Author(s)	Type of Study	Number of Patients	Control vs. Intervention or Comparator vs. Treatment	Follow-up Period	Outcome Measures	Comment(s)	Methodological Quality Scoring
Manchikanti et al (106)	R, AC, F	40 Local anesthetic only = 20 Local anesthetic with steroids = 20	6 mL of local anesthetic only or 6 mL of local anesthetic with 6 mg of nonparticulate betamethasone.	One year	NRS, ODI, employment status, opioid intake	Significant improvement with 50% or more pain relief and functional status improvement in 80% and 85% at one year in patients receiving local anesthetic or local anesthetic with steroids. This is the first randomized trial conducted in thoracic pain patients in contemporary practice under fluoroscopy.	11/12
Ayad & El Masry (107)	P, B	21	8 patients underwent conservative management whereas 13 patients underwent epidural injections with clonidine 150 mg, 80 mg of methylprednisolone acetate diluted in 8 mL of 0.5% lidocaine.	6 months	VAS, sleep patterns, appetite changes, ADL	In this evaluation, allodynia in patients with post thoracotomy syndrome at least after 2 months were included for injection therapy with epidural injections. There was significant improvement which was different from the control group in patients receiving epidural injections. Sleep scores, appetite changes, activity scores also improved. Over 50% of the patients showed significant improvement of 50% or more. This study had multiple issues with inclusion criteria including the number of patients as well as duration of pain.	7/10

VAS = Visual Analog Scale; ODI = Oswestry Disability Index; ADL = Activities of Daily Living; NRS = Numeric Rating Scale

Source: Benyamin RM, et al. A systematic evaluation of thoracic interlaminar epidural injections. *Pain Physician* 2012; 15:E497-E514 (16).

Evidence

For caudal epidural injections, there was good evidence for short- and long-term relief of chronic pain secondary to disc herniation or radiculitis with local anesthetic and steroids and fair relief with local anesthetic only. Further, this systematic review also provided indicated evidence of fair for caudal epidural injections in managing chronic axial or discogenic pain, spinal stenosis, and post surgery syndrome.

For lumbar interlaminar epidural injections, there was good evidence when performed under fluoroscopy for radiculitis secondary to disc herniation with local anesthetic and steroids, fair with local anesthetic only, fair for radiculitis secondary to spinal stenosis with local anesthetic and steroids, and fair for axial pain without disc herniation with local anesthetic with or without steroids.

For lumbar transforaminal lumbar epidural steroid injections, the evidence is good for radiculitis secondary to disc herniation with local anesthetics and steroids and fair with local anesthetic only; it is fair for radiculitis secondary to spinal stenosis with local anesthetic and steroids; and limited for axial pain and post surgery syndrome using local anesthetic with or without steroids.

For cervical interlaminar epidural injections, the evidence is good for radiculitis secondary to disc herniation with local anesthetics and steroids, fair with local anesthetic only, and fair for local anesthetics with or without steroids, for axial or discogenic pain, pain of central spinal stenosis, and pain of post surgery syndrome.

For thoracic interlaminar epidural injections the evidence for thoracic epidural injection in treating chronic thoracic pain is considered fair and limited for post thoracotomy pain. 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.

Indication and Medical Necessity

- Common indications for caudal epidural 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.

- Common indications for lumbar interlaminar epidural 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
    - 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.

- Common indications for lumbar transforaminal epidural are as follows:
  - Chronic low back and/or lower extremity pain (unilateral involvement) which has failed to respond or poorly responded to noninterventional and nonsurgical conservative management resulting from:
    - disc herniation/lumbar radiculitis
    - lumbar spinal stenosis.
  - Intermittent or continuous pain causing functional disability.
  - Average pain level of ≥ 6 on a scale of 0 to 10.

- Common indications for cervical epidural injections are as follows:
  - Chronic neck and/or upper extremity pain which has failed to respond or poorly responded to non-interventional and nonsurgical conservative management resulting from:
    - disc herniation/cervical radiculitis
    - cervical spinal stenosis
    - post cervical surgery syndrome
    - degenerative disc disease/discogenic 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.

♦ Common indications for thoracic interlaminar epidurals 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:
    - disc herniation/thoracic radiculitis
    - thoracic spinal stenosis
    - thoracic post-surgery syndrome
    - degenerative disc disease/discogenic 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.

Frequency of Interventions

♦ In the diagnostic phase, a patient may receive 2 injections at intervals of no sooner than one week or preferably 2 weeks, except for blockade in cancer pain or when a continuous administration of local anesthetic is employed for reflex sympathetic dystrophy.

♦ In the therapeutic phase (after the diagnostic phase is completed), the frequency of interventional techniques should be 3 months or longer between each injection, provided that no less than 50% relief is obtained for at least 2 months. However, if the neural blockade is applied for different regions, it can be performed at intervals of no sooner than one week and preferably 2 weeks for most types of blocks. The therapeutic frequency must remain at least 3 months for each region. Further all regions are to be treated at the same time, provided all procedures are performed safely.

♦ In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary judging by the medical necessity criteria, and these should be limited to a maximum of 4.

♦ Under unusual circumstances with a recurrent injury, carcinoma, or reflex sympathetic dystrophy, blocks may be repeated at intervals of 8 weeks after diagnosis-stabilization in the treatment phase.

FACET JOINT INJECTION/ABLATIVE TREATMENT

Cigna criteria is as follows:

Diagnostic

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)

Therapeutic

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.

It is surprising that Cigna does not cover therapeutic facet joint injections. In fact, evidence may even be superior to facet joint injections in the relief obtained by them compared to radiofrequency neurotomy.

In addition, the cost effectiveness is the same. Either one performs 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.

In reference to the ablative treatment, Cigna policy states the following:

Cigna covers initial radiofrequency denervation of paravertebral facet joint nerves (also referred to as radiofrequency neurolysis, neurotomy, facet rhizotomy) (CPT codes 64633-64636) for the treatment of chronic back or neck pain as medically necessary when ALL of the following criteria are met:

- Pain is exacerbated by extension and rotation, or is associated with lumbar rigidity
- 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 denervation 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 or maintenance denervation of paravertebral facet joint nerves for any indication because it is considered not medically necessary.

Cigna does not cover ANY of the following ablative procedures for the treatment of back or neck pain because each is considered experimental, investigational or unproven (this list may not be all-inclusive);

- Pulsed radiofrequency (CPT code 64999)
- Cryoablation/cryoneurolysis/cryodenervation (CPT code 64999)
- Chemical ablation (e.g., alcohol, phenol, glycerol) (CPT codes 64622-64627)
- Laser ablation (CPT code 64999)
- Sacroiliac (SI) joint nerve ablation by any method (CPT code 64640)

Cigna covers radiofrequency neurotomy; however, only for a total of 1 year.

Diagnostic Cervical Facet Joint Interventions
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 (25,26). The diagnostic blocks applied in the precision diagnosis of chronic neck pain include cervical facet joint nerve blocks and cervical provocation discography.

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 (108-111). Facet joints have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity (23,25,112-121). 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 (23,25,26,122-128).

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 (23,25,110,122,129). Construct validity of facet joint blocks is important to eliminate placebo effect as the source of confounding results and to secure true-positive results (23,25,112-121). 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 (5,23,25,129-131).

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 (25,117,132-136).

The systematic review by Falco et al (25) of diagnostic cervical facet joint nerve blocks, utilizing 9 studies (112-117,119-121) with ≥ 75% 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. In addition, the prevalence was shown to be 36% with 95% CI of 22% to 51% in patients after surgical intervention (118).

The systematic review by Falco et al (25) showed false-positive rates with a single block of 27% to 63% with CIs ranging from 15% to 78% (Table 12) (112-117,119-121,137-139).

Table 12. *Data of prevalence and false-positive rates of pain* of *cervical facet joint origin based on diagnostic blocks.*

Study	% Relief Used	Methodological Criteria Score	Number of Subjects	Prevalence Estimates with 95% Confidence Intervals	False-Positive Rate with 95% Confidence Intervals
50% - 74% WITH SINGLE BLOCK					
Cohen et al (137)	≥ 50%	5/12	24	55% with low volume and 25% with high volume	NA
75%-100% WITH SINGLE BLOCK					
Aprill & Bogduk (138)	≥ 90%	6/12	318	25%-63%	NA
Bogduk & Aprill (139)	≥ 90%	6/12	56	41%-64%	NA
75%-100% WITH CONTROLLED BLOCKS					
Yin & Bogduk (112)	≥ 80%	9/12	143	55% (95% CI, 38%, 62%)	NA
Manchukonda et al (113)	≥ 80%	9/12	251 of 500	39% (95% CI, 32%, 45%)	45% (95% CI 37%, 52%)
Manchikanti et al (114)	≥ 80%	9/12	255 of 500	55% (95% CI, 49%, 61%)	63% (95% CI 54%, 72%)
Manchikanti et al (115)	≥ 80%	9/12	120	67% (95% CI 58%, 75%)	63% (95% CI 48%, 78%)
Manchikanti et al (116)	≥ 75%	9/12	106	60% (95% CI, 50%, 70%)	40% (95% CI, 34%, 46%)
Speldewinde et al (117)	≥ 90%	9/12	97	36% (95% CI, 27%, 45%)	NA
Barnsley et al (120)	≥ 90%	9/12	50	54% (95% CI, 40%, 68%)	NA
Lord et al (119)	≥ 90%	9/12	68	60% (95% CI, 46%, 73%)	NA
Barnsley et al (121)	≥ 90%	9/12	55	NA	27% (95% CI, 15%, 38%)

NA = Not Available or Not Applicable; CI = Confidence Interval; * = Adjusted

Source: Falco FJE, et al. An updated review of diagnostic utility of cervical facet joint injections. *Pain Physician* 2012; in press (25).

Further, Rubinstein and van Tulder (23), 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 (5,8,9,23,25,130), 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 the therapeutic phase. The therapeutic phase starts after completion of the 2 diagnostic facet joint blocks, that is essentially a third visit for interventional procedures.

Diagnostic Thoracic Facet Joint Interventions

Atluri et al (21), in a systematic review, evaluated the diagnostic accuracy of thoracic facet joint nerve blocks in the assessment of chronic upper back and mid back pain. They concluded that the evidence for the diagnostic accuracy of thoracic facet joint injections is good.

Table 13 shows data of the prevalence of thoracic joint pain by controlled diagnostic blocks (113,114,140).

Table 13. *Data of prevalence of thoracic joint pain by controlled diagnostic blocks.*

Study	% Relief Used	Methodological Criteria Score	Number of Subjects	Prevalence Estimates	False-Positive Rate
Manchikanti et al (140)	≥ 80%	10/12	46	48% (95% CI; 34%-62%)	58% (95% CI; 38%-78%)
Manchikanti et al (114)	> 80%	10/12	72	42% (95% CI; 30%-53%)	55% (95% CI; 38%-78%)
Manchukonda et al (113)	> 80%	10/12	65	34% (95% CI; 22%-47%)	42% (95% CI; 36%-53%)
COMBINED RESULTS	__	10/12	183	40% (95% CI; 33%-48%)	42% (95% CI; 33%-51%)

Source: Atluri S, et al. Diagnostic accuracy of thoracic facet joint nerve blocks: An update of the assessment of evidence. *Pain Physician* 2012; 15:E483-E496 (21).

Diagnostic Lumbar Facet Joint Interventions

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 (5,24). The diagnostic facet joint nerve blocks are applied in the precision diagnosis of chronic low back pain.

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 (5,24,108,141-146). Facet joints have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity (5,24,113-115,129,147-154). 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 (5,24,155,156).

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 (5,24,129). Construct validity of facet joint blocks is important to eliminate placebo effect as the source of confounding results and to secure true-positive results (5,24,129,157). The hypothesis that testing a patient first with lidocaine and subsequently with bupivacaine as a means of identifying the placebo response has been tested and proven (129-131,157,158).

The specificity of the effect of lumbar facet joint blocks was demonstrated in controlled trials (159,160). Provocation response of facet joint pain was shown to be unreliable in one study (161).

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 (161-164). 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 (134,165) and lack of influence of psychological factors on the validity of controlled lumbar diagnostic local anesthetic blocks of facet joints was demonstrated (132,166). Other variables including prior opioid exposure were also evaluated (133,167,168).

Data of prevalence of lumbar facet joint by diagnostic blocks is illustrated in Table 14 (113-115,148-154,163,169-182).

Based on the systematic review by Falco et al (27), diagnostic lumbar facet joint nerve blocks, utilizing 13 studies (113-115,148,150,154,163,176-182) with ≥75% pain relief and ability to perform previously painful movement with controlled diagnostic blocks, estimated prevalence as 25% to 45% in heterogenous populations. False-positive rates of 17% to 49% are demonstrated.

Table 14. *Data of prevalence of lumbar facet joint pain by diagnostic blocks.*

Study	Methodological Criteria Score	Number of Subjects	Prevalence Estimates with 95% Confidence Intervals	False-Positive Rate with 95% Confidence Intervals
SINGLE BLOCKS WITH 50%-74% RELIEF				
Pang et al, 1998 (169)	9/12	100	Prevalence 48%	NA
SINGLE BLOCKS WITH ≥75%-100% RELIEF				
Revel et al, 1992 (170)	8/10	51	33%	NA
Revel et al, 1998 (171)	8/10	80	31%	NA
Young et al, 2003 (172)	11/12	102	61%	NA
Manchikanti et al, 2010 (163)	11/12	491	53% (67%-80%)	NA
CONTROLLED BLOCKS WITH 50%-74% RELIEF				
Schwarzer et al, 1994 (151,152,173)	11/12	176	NA	38% (30%-46%)
Schwarzer et al, 1995 (153,174)	12/12	57 of 63	40% (27% - 53%)	NA
Manchikanti et al, 2000 (149)	12/12	200	42% (35% - 42%)	37% (32% - 42%)
Manchikanti et al, 2010 (163)	11/12	181	61% (53%-81%)	17% (10%- 24%)
Schütz et al, 2011 (175)	11/12	60	NA	66%
CONTROLLED BLOCKS WITH ≥75%-100% RELIEF				
Manchikanti et al, 2001 (176)	11/12	120	40% (31%–49%)	47% (35%-59%)
Manchikanti et al, 1999 (148)	11/12	120	45% (36% - 54%)	41% (29% - 53%)
Manchikanti et al, 2000 (177)	12/12	180	36% (29% - 43%)	25% (21% - 39%)
Laslett et al 2004, 2006 (178,179)	12/12	151	24.2%	NA
Manchikanti et al, 2003 (150)	11/12	300 I: Single region II: Multiple regions	I: 21% (14%-27%) II: 41% (33%-49%)	I: 17% (10%-24%) II: 27% (18%-36%)
Manchikanti et al, 2002, (115)	11/12	120	40% (31% - 49%)	30% (20% - 40%)
Manchikanti et al, 2004 (114)	11/12	397	31% (27% - 36%)	27% (22% - 32%)
Manchukonda et al, 2007 (113)	11/12	303	27% (22% - 33%)	45% (36% - 53%)
Manchikanti et al, 2007 (154)	11/12	117	16% (9%–23%)	49% (39%–59%)
Manchikanti et al, 2010 (163)	11/12	491	31% (26% - 35%)	42% (35% - 50%)
DePalma et al, 2011 (180)	11/12	156	31% (24% - 38%)	NA
Manchikanti et al, 2001 (181)	11/12	100 I: (≤65 years) = 50 II: (≥65 years) = 50	I: 30% (17%-43%) II: 52% (38%-66%)	I: 26% (11%-40%) II: 33% (14%-35%)
Manchikanti et al, 2001 (182)	11/12	100 I: (BMI<30) = 50 II: (BMI ≥30) = 50	I: 36% (22%, 50%) II: 40% (26%, 54%)	I: 44% (26%, 61%) II: 33% (16%, 51%)

NA = Not Available

Source: Falco FJE, et al. An update of systematic assessment of diagnostic accuracy of lumbar facet joint nerve blocks. *Pain Physician* 2012; in press (27).

The evidence showed there is good evidence for diagnostic facet joint nerve blocks with 75% to 100% pain relief as the criterion standard with dual blocks, with fair evidence with 50% to 74% pain relief as the criterion standard with controlled diagnostic blocks; however, the evidence is limited with single diagnostic blocks of either 50% to 74%, or 75% or more pain relief as the criterion standard.

The recommendations are as follows:

Based on true evidence-based guidelines (5,8,9,24,27), diagnostic lumbar facet joint nerve blocks are recommended in patients with suspected facet joint pain.

In summary, based on the overwhelming evidence, 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 the therapeutic phase. The therapeutic phase starts after completion of the 2 diagnostic facet joint blocks, that is essentially a third visit for interventional procedures.

Evidence

The evidence is good for the diagnostic accuracy of cervical facet joint interventions; however, the evidence is limited for a single diagnostic block with 50% to 74% pain relief as the criterion standard, whereas no studies were available assessing the accuracy of 50% to 74% pain relief as the criterion standard with controlled blocks. The evidence for 75% to 100% pain relief as the criterion standard with a single block is limited (25).

Atluri et al (21), in a systematic review, evaluated the diagnostic accuracy of thoracic facet joint nerve blocks in the assessment of chronic upper back and mid back pain. They concluded that the evidence for the diagnostic accuracy of thoracic facet joint injections is good.

The evidence showed there is good evidence for diagnostic lumbar facet joint nerve blocks with 75% to 100% pain relief as the criterion standard with dual blocks with fair evidence with 50% to 74% pain relief as the criterion standard with controlled diagnostic blocks; however, the evidence is limited with single diagnostic blocks of either 50% to 74%, or 75% or more pain relief as the criterion standard (27).

Indications

- Common indications for diagnostic facet joint interventions are as follows:
  - Somatic or nonradicular low back, neck, midback, or upper back and/or lower extremity, upper extremity, chest wall pain or cervicogenic headache
  - 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 nonsteroidal anti-inflammatory agents
  - Lack of evidence, either for discogenic or sacroiliac joint pain
  - Lack of disc herniation or evidence of radiculitis
  - 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
  - Contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate nonsteroidal anti-inflammatory drugs
- Positive response to controlled local anesthetic blocks (< 1mL) with a criterion standard of 80% pain relief and the ability to perform prior painful movements without any significant pain

Frequency of Interventions

Two diagnostic facet joint nerve blocks must be performed prior to embarking onto the therapeutic phase. The therapeutic phase starts after completion of the 2 diagnostic facet joint blocks, that is essentially a third visit for interventional procedures.

Therapeutic Cervical Facet Joint Injections

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.

Tables 15-17 illustrate the results of cervical facet joint interventions (122-126,183-189).

Table 15. *Results of randomized trials and observational studies of cervical facet joint nerve blocks.*

Study Study Characteristics Methodological Quality Scoring	Participants	Pain Relief			Results	
		3 mos.	6 mos.	12 mos.	Short-Term Relief ≤ 6 months	Long-Term Relief > 6 months
Manchikanti et al, 2008, 2010, 2006 (122,123,183) RA, DB, AC 11/12	Group I-no steroid = 60 Group II-steroid = 60	83% versus 85%	87% versus 95%	85% versus 92%	*P*	*P*
Manchikanti et al, 2004 (124) P 7/12	100	92%	82%	56%	*P*	*P*

RA = Randomized; DB = Double-Blind; AC = Active Control; P = Prospective; *P* = Positive

Source: Falco FJE, et al. Systematic review of therapeutic effectiveness of cervical facet joint interventions: An update. *Pain Physician* 2012; in press (26).

Table 16. *Results of randomized trials of cervical intraarticular injections.*

Study Study Characteristics Methodological Quality Scoring	Participants	Pain Relief			Results	
		3 mos.	6 mos.	12 mos.	Short-Term Relief ≤ 6 months	Long-Term Relief > 6 months
Park & Kim, 2012 (184) RA, AC 6/12	200	SPP	SPP	SPP	U	U
Barnsley et al, 1994 (185) RA, DB, AC 12/12	41	20%	20%	20%	N	N

RA = Randomized; DB = Double-Blind; AC = Active-Control; SPP = Significant Proportion of Patients; N = negative; U = Unclear

Source: Falco FJE, et al. Systematic review of therapeutic effectiveness of cervical facet joint interventions: An update. *Pain Physician* 2012; in press (26).

At present, in the literature, one well performed randomized double-blind trial has been published in 3 publications (122,123) with one-year follow-up, and 2-year follow-up. There is also one prospective evaluation (124). Falco et al (26) reviewed the evidence from all the available publications on medial branch blocks and included a randomized trial and observational study in their evaluation (124).

Table 17. *Results of randomized trials and observational studies of cervical conventional radiofreqency neurotomy.*

Study Study Characteristics Methodological Quality Scoring	Participants	Pain Relief			Results	
		3 mos.	6 mos.	12 mos.	Short-Term Relief ≤ 6 months	Long-Term Relief > 6 months
Lord et al, 1996 (125) RA, Sham control, DB 11/12	24	NA	1 of sham 7 of active	58% in active treatment group	*P*	*P*
Sapir and Gorup, 2001 (126) P 7/12	46	NA	NA	Mean VAS change 4.6 ± 1.8	*P*	*P*
Macvicar et al, 2012 (186) P 7/12	104	NA	74% & 61%	74% & 61%	*P*	*P*
Speldewinde, 2011 (187) P 7/12	130	NA	76%	76%	*P*	*P*
Govind et al, 2003 (188) P 7/12	49	NA	88%	88%	*P*	*P*
Cohen et al, 2007 (189) R 7/12	92	NA	55%	55%	*P*	*P*

RA = Randomized; DB = Double-Blind; P = Prospective; R = Retrospective; vs = Versus; *P* = Positive

Source: Falco FJE, et al. Systematic review of therapeutic effectiveness of cervical facet joint interventions: An update. *Pain Physician* 2012; in press (26).

With reference to radiofrequency neurotomy: for cervical radiofrequency neurotomy there was only one randomized trial which met inclusion criteria (126), and 3 observational studies (126-128).

Cost Effectiveness

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 the lumbar spine, which is equivalent to the number of cervical medial branch blocks, increasing the cost substantially.

Therapeutic Thoracic Facet Joint Injections

Manchikanti et al (22), in a systematic review, evaluated the clinical utility of therapeutic thoracic facet joint interventions in the therapeutic management of chronic upper back and mid back pain. They concluded that the evidence for therapeutic facet joint interventions is fair for medial branch blocks, whereas it is not available for intraarticular injections, and limited for radiofrequency neurotomy due to the lack of literature.

Table 18 illustrates the results of randomized and observational studies of thoracic facet joint interventions (187,190-194).

Table 18. *Results of randomized and observational studies of thoracic facet joint interventions.*

Study **Study Characteristics** **Methodological Quality Scoring**	**Participants**	**Pain Relief**			**Results**	
		3 mos.	**6 mos.**	**12 mos.**	**Short-Term Relief ≤ 6 months**	**Long-Term Relief > 6 months**
MEDIAL BRANCH BLOCKS						
Manchikanti et al, 2008, 2010, 2012 (190-192) RA, DB 10/12	Group I - no steroid = 50 Group II- steroid = 50	79% vs 83%	79% vs 81%	80% vs 83%	*P*	*P*
Manchikanti et al, 2006 (193) P 7/13	55 consecutive patients, all meeting diagnostic criteria for thoracic facet joint pain	71%	71%	71%	*P*	*P*
CONVENTIONAL RADIOFREQUENCY NEUROTOMY						
Stolker et al, 1993 (194) P 8/13	40 patients with thoracic pain were evaluated	N/A	N/A	64%	N/A	*P*
Speldewinde, 2011 (187) P 7/13	28 patients with thoracic pain as part of outcomes of percutaneous zygapophysial and sacroiliac joint neurotomy in a community setting with total of 379 patients included	N/A	N/A	64%	*P*	*P*

RA = Randomized; DB = Double-Blind; P = Prospective; O = Observational; vs = Versus; *P* = Positive

Source: Manchikanti KN, et al. An update of evaluation of therapeutic thoracic facet joint interventions. *Pain Physician* 2012; 15:E463-E481 (22).

Therapeutic Lumbar Facet Joint Injections

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.

Tables 19 to 21 illustrate the results of therapeutic studies (156,187,195-218).

Table 19. *Effectiveness of conventional and pulsed lumbar radiofrequency neurotomy.*

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comments
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	≥ 1 year	
RANDOMIZED									
Civelek et al, 2012 (195) RA, AC 9/12	100	CRF = 50 Facet joint nerve blocks = 50	NA	92% vs. 75%	90% vs. 69%	NA	*P*	*P*	Positive short and long-term results
Cohen et al, 2010 (196) RA, DB 8/12	"0" block = 51 One block = 20 Two blocks = 14	CRF	"0" group = 33% One block = 39% Two blocks = 64%	NA	NA	*P* in two block group	NA	NA	Positive short-term results with dual blocks
Nath et al, 2008 (155) RA, DB, Sham control 12/12	40	Radiofrequency = 20 Sham = 20	NA	Significant proportion of patients in interventional group	NA	P for radiofrequency N for sham or active	P for radiofrequency N for sham	NA	Positive short and long-term
Tekin et al, 2007 (197) RA, AC and sham, DB 12/12	60	CRF = 20 PRF = 20 Control = 20	NA	SI with CRF	SI with CRF	NA	P for radiofrequency N for sham	P for radiofrequency N for sham	Positive short and long-term results
van Wijk et al, 2005 (198) RA, DB, Sham control 12/12	81	Radiofrequency = 40 Sham = 41	27.5% vs. 29.3%	27.5% vs. 29.3%	27.5% vs. 29.3%	N	N	N	Negative results
Dobrogowski et al, 2005 (199) RA, AC 10/12	45	CRF	NA	60%	NA	NA	*P*	NA	Positive short and long-term results
van Kleef et al, 1999 (200) RA, DB, sham control 12/12	31	Radiofrequency = 15 Sham = 16	60% vs. 25%	47% vs. 19%	47% vs. 13%	P for radiofrequency N for sham or active	P for radiofrequency N for sham	P for radiofrequency N for sham	Positive short and long-term results
OBSERVATIONAL									
Masala et al, 2012 (201) O 7/12	92	PRF	NA	100%	100%	NA	*P*	*P*	Positive short and long-term results

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comments
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	≥ 1 year	
Tomé-Bermejo et al, 2011 (202) P 7/12	86	CRF	89%	66%	50%	*P*	*P*	*P*	Positive short and long-term results
Speldewinde, 2011 (187) P 7/12	151	CRF	69%	69%	69%	*P*	*P*	*P*	Positive short and long-term results
Yilmaz et al, 2010 (203) R 7/12	50	CRF	NA	NA	86%	NA	NA	*P*	Positive short and long-term results
Son et al, 2010 (204) R 7/12	60	CRF	NA	60%	60%	NA	*P*	*P*	Undeterminate short and long-term results
Gofeld et al, 2007 (205) Clinical audit 7/13	174	CRF	NA	68.4%	96.4%	*P*	*P*	*P*	Positive short and long-term results
Martinez- Suáarez et al, 2005 (206) O 6/12	252	CRF	NA	NA	75%	NA	NA	*P*	Positive short and long-term results
Tzaan & Tasker, 2000 (207) R 7/12	69	CRF	NA	41%	NA	NA	U	NA	Positive short and long-term results

RA = Randomized; DB = Double-Blind; AC = Active Control; R = Retrospective; O = Observational; P = Prospective; SI = Significant Improvement; CRF = Conventional Radiofreqency Neurotomy; PRF = Pulsed Radiofreqency Neurotomy; *P* = Positive; N = Negative; NA= Not Applicable; U = Undetermined

Source: Falco FJE, et al. An update of effectiveness of therapeutic lumbar facet joint interventions. *Pain Physician* 2012; in press (28).

Table 20. *Effectiveness of therapeutic lumbar facet joint nerve blocks.*

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comments
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	≥ 1 year	
Civelek et al 2012 (195) RA, AC 9/12	100	LA with steroid = 50 CRF = 50	NA	75% vs. 92%	69% vs. 90%	NA	P	P	Positive short and long-term results
Manchikanti et al 2007, 2008, 2010 (156,208,209) RA, DB, AC 11/12	120	LA with steroid = 60 LA = 60	82% vs. 83%	93% vs. 83%	85% vs. 84%	P	P	P	Positive with local anesthetic with or without steroids
Manchikanti et al 2001 (210) RA, AC 8/12	73	LA with steroid = 41 LA = 32	SI	SI	SI	P	P	P	Positive short and long-term results

RA = Randomized; DB = Double-Blind; AC = Active Control; CRF = Conventional Radiofrequency Neurotomy; ST = Steroid; LA = Local Anesthetic; SAL = Saline; SI = Significant Improvement; P=Positive; N=Negative; NA = Not Applicable

Source: Falco FJE, et al. An update of effectiveness of therapeutic lumbar facet joint interventions. *Pain Physician* 2012; in press (28).

Table 21. *Effectiveness of lumbar intraarticular injections.*

Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment(s)
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos	≥ 1 year	
RANDOMIZED									
Carette et al 1991 (211) RA, DB, PC or AC Single block confirmed 11/12	97	Methylprednisolone acetate = 49 Isotonic saline = 48 patients	33% vs 42%	22% vs 10%	NA	N	N	NA	Negative results
Fuchs et al 2005 (212) R, DB, AC 8/12	60	Hyaluronic acid versus glucocorticoid with 6 injections.	Significant proportion of patients	Significant proportion of patients	NA	U	U	NA	Undetermined
OBSERVATIONAL									
Murtagh 1988 (213) P 7/12	100	Local anesthetic and steroids	54%	NA	NA	*P*	NA	NA	Positive short-term results
Destouet et al 1982 (214) O 7/12	54	Local anesthetic and steroids	54%	38%	38%	*P*	N	N	Positive short-term with a single block
Lippitt 1984 (215) R 7/12	99	Local anesthetic and steroids	51%	NA	NA	*P*	NA	NA	Positive short-term with a single block
Celik et al 2011 (216) P 7/13	80	Conservative vs. local anesthetic and steroid	Significant proportion of patients in treatment group	Significant proportion of patients	NA	*P*	*P*	NA	Positive short-term and long-term results
Anand & Butt 2007 (217) P 7/12	57	Local anesthetic and steroids	53%	68%	NA	*P*	*P*	NA	Positive short-term and long-term results
Bani et al 2002 (218) R 7/12	230	Local anesthetic and steroids	NA	NA	18.7%	NA	NA	N	Negative

RA = Randomized; DB = Double-Blind; AC = Active Control; PC = Placebo Control; R = Retrospective; O = Observational; P = Prospective; LA = Local Anesthetic; HA = Hyaluronidase; ST = Steroid; SAL = Saline; *P*=Positive; N=Negative; NA= Not Applicable; U = Undetermined

Source: Falco FJE, et al. An update of effectiveness of therapeutic lumbar facet joint interventions. *Pain Physician* 2012; in press (28).

Cost Effectiveness
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.

Evidence of Therapeutic Facet Joint Interventions
Based on the above discussion, we request that Cigna change the policy to cover the therapeutic medial branch blocks which are as cost-effective, along with radiofrequency neurotomy, on a long-term basis rather than limiting for one year.

Falco et al (26), in a systematic review, evaluated the effectiveness of therapeutic cervical facet joint interventions. They concluded that the indicated evidence for cervical radiofrequency neurotomy is fair. The indicated evidence for cervical medial branch blocks is fair. The indicated evidence for cervical intraarticular injections with local anesthetic and steroids is limited.

Manchikanti et al (22), in a systematic review, evaluated the clinical utility of therapeutic thoracic facet joint interventions in the therapeutic management of chronic upper back and mid back pain. They concluded that the evidence for therapeutic facet joint interventions is fair for medial branch blocks, whereas it is not available for intraarticular injections, and limited for radiofrequency neurotomy due to the lack of literature.

Falco et al (28), in a systematic review, evaluated the effectiveness of therapeutic lumbar facet joint interventions. They concluded that there is good evidence for the use lumbar facet joint nerve blocks and of conventional radiofrequency neurotomy, and fair to good evidence for lumbar facet joint nerve blocks for the treatment of chronic lumbar facet joint pain with short-term and long-term pain relief and functional improvement. There is limited evidence for intraarticular facet joint injections and pulsed radiofrequency thermoneurolysis.

Indications
- Common indications for therapeutic facet joint interventions are:
  - Somatic or nonradicular low back and/or lower extremity pain; mid back, upper back, or chest wall pain; and neck pain, suspected cervicogenic headache, and/or upper extremity pain
  - Duration of pain of at least 3 months with average pain levels of 6 or greater on a scale of 0 – 10
  - Intermittent or continuous pain causing functional disability
  - Failure to respond to more conservative management, including physical therapy modalities with exercises, chiropractic management, and nonsteroidal antiinflammatory agents
  - Lack of evidence, either for discogenic or sacroiliac joint pain, lack of disc herniation or evidence of radiculitis
  - No contraindications with understanding of consent, nature of the procedure, needle placement, or sedation
  - No history of allergy to contrast administration, local anesthetics, steroids, or other drugs potentially utilized
  - Contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate nonsteroidal anti-inflammatory drugs
  - Positive response to controlled, comparative local anesthetic blocks with at least 80% relief with < 1 mL of anesthetic per level

Frequency of Interventions

- Injections do not exceed a frequency parameter of more than once every 2 months for a specific region (cervical/thoracic, lumbosacral).
- Documented initial pain relief in the diagnostic phase of over 75% or 80% with ability to perform previously painful maneuvers concordant with the duration of local anesthetic.
- In the therapeutic phase, with therapeutic facet joint nerve block injections, the persistent pain relief of ≥ 50% must be documented for a minimum of 2 months.
- Appropriate consideration is given to the adverse effects (e.g., adrenal suppression of corticosteroid injections).
- A positive response to controlled local anesthetic blocks (<1 mL per nerve) with a criterion standard of at least 75% or 80% pain relief with ability to perform prior painful movements without any significant pain.
    - In the diagnostic phase, a patient may receive 2 procedures at intervals of no sooner than one week or preferably 2 weeks, with careful judgment of response.
- In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency would be 3 months or longer between injections, provided that ≥ 50% relief is obtained for 2 months.
- If the interventional procedures are applied for different regions, they may be performed at intervals of no sooner than one week or preferably 2 weeks for most types of procedures.
    - It is suggested that therapeutic frequency remain at least a minimum of 2 months for each region, it is further suggested that all the regions be treated at the same time provided that all procedures can be performed safely.
    - In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary according to the medical necessity criteria, and these be limited to a maximum of 4 times for local anesthetic and steroid blocks over a period of one year, per region.
    - Cervical and thoracic areas are considered as one region and lumbar and sacral areas are considered as one region for billing purposes.

SACROILIAC (SI) JOINT INJECTION

The policy states as follows:

> **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

There is evidence showing that sacroiliac joint interventions are neither experimental nor investigational.

Diagnostic Sacroiliac Joint Interventions

Simopoulos et al (17), in a systematic review, evaluated the accuracy of diagnostic sacroiliac joint interventions. They concluded that the evidence for the diagnostic accuracy of sacroiliac joint injections is good, the evidence for provocation maneuvers is fair, and evidence for imaging is limited.

Table 22 illustrates data of the prevalence of sacroiliac joint pain by controlled diagnostic blocks (169,172,176,180,219-233).

Table 22. *Data of prevalence of sacroiliac joint pain by controlled diagnostic blocks.*

Study	% Relief Used	Methodological Criteria Score	Number of Subjects	Prevalence Estimates	False-Positive Rate
50%-79% RELIEF WITH A SINGLE BLOCK					
Schwarzer et al (219)	75%	9/11	43	30%	---
Maigne & Planchon (220)	75%	8/11	40	35%	---
Broadhurst & Bond (221)	70%	11/11	40	NA	---
50%-79% RELIEF WITH A DUAL BLOCK					
Maigne et al (222)	75%	8/11	54	18.5%	20%
Irwin et al (223)	70%	8/11	158	26.6%	NA
DePalma et al (180,224)	75%	8/11	156	18.2%	NA
DePalma et al (225)	75%	8/11	27	18.2%	NA
DePalma et al (226)	75%	8/11	170	18.2%	NA
van der Wurff et al (227)	50%	9/11	60	38%	21%
Liliang et al (228)	75%	8/11	52	40.4%	26%
80%-100% RELIEF WITH A SINGLE BLOCK					
Pang et al (169)	90%	8/11	104	10%	---
Dreyfuss et al (229)	90%	8/11	85	53%	---
Slipman et al (230)	80%	8/11	50	62%	---
Laslett et al (231)	80%	8/11	48	33%	---
Young et al (172)	80%	8/11	81	39%	---
Stanford & Burnham (232)	80%	6/11	34	32%	---
80%-100% RELIEF WITH DUAL BLOCKS					
Manchikanti et al (176)	80%	9/11	20	10%	22%
Laslett et al (233)	80%	8/11	43/48	25.6%	NA

NA = Not Available

Source: Simopoulos TT, Manchikanti L, Singh V, Gupta S, Hameed H, Diwan S, Cohen SP. A systematic evaluation of prevalence and diagnostic accuracy of sacroiliac joint interventions. *Pain Physician* 2012; 15:E305-E344 (17).

Therapeutic Sacroiliac Joint Interventions

Hansen et al (18), in a systematic review, evaluated the clinical utility of sacroiliac joint interventions.

Tables 23-25 illustrate the results of studies of therapeutic sacroiliac joint interventions (234-244).

Table 23. *Results of randomized and observational studies of effectiveness of intraarticular sacroiliac joint injections.*

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	1 year	
Hawkins & Schofferman (234) NR, F 7/13	155	Local anesthetic and steroids Number of injections= 1 to 4	77%	77%	77%	P	P	P	Positive study
Liliang et al (235) NR, F 8/13	150	Local anesthetic and steroids Number of injections = 1 to 3	66.7%	NA	NA	P	NA	NA	Positive study
Kim et al (236) R, AC, F 11/12	50 Prolotherapy group = 24 Steroid group = 26	25% dextrose solution with levobupivacaine or levobupivacaine with triamcinolone Number of injections = 3	Prolotherapy = 77.6% vs. Steroids = 70.5%	Prolotherapy = 63.6% vs. Steroids = 27.2%	Prolotherapy = 58.7% vs. Steroids = 10.2%	P*	N = steroids P* = local anesthetic	N = steroids P* = local anesthetic	Positive for prolotherapy
Borowsky & Fagen (237) NR, F 6/10	120	Intraarticular or with extraarticular injection Number of injections= 1	12.5 % vs. 31.25%	NA	NA	N	N	N	Negative study

*Prolotherapy; R = Randomized; F = Fluoroscopy; AC = Active-control; NR = Non-Randomized; P = Positive; N = Negative; NA = Not Applicable

Source: Hansen H, et al. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. *Pain Physician* 2012; 15:E247-E278 (18).

Table 24. *Results of randomized and observational studies of effectiveness of periarticular sacroiliac joint injections.*

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	1 year	
Luukkainen et al (238) R, B, AC 11/12	24	Methylprednisolone with local anesthetic vs sodium chloride solution Number of injections = 1	Significant improvement in steroid group	NA	NA	P	NA	NA	Positive for steroids with local anesthetic
Lee et al (239) R, AC, F 12/12	39 patients Botox group (n=20) Steroid group (n=19)	Number of injections = 1	Botox = 88.2% versus steroid = 26.7%	NA	NA	N = steroids P** = local anesthetic	NA	NA	Positive for Botox
Luukkainen et al (240) R, B, AC 11/12	20	Methylprednisolone with local anesthetic vs. sodium chloride solution Number of injections = 1	Significant improvement in steroid group	NA	NA	P	NA	NA	Positive for steroid
Borowsky and Fagen (237) NR,F 6/10	120	Intraarticular and periarticular Number of injections = 1	12.5 % vs 31.25%	NA	NA	N	NA	NA	Small study with negative results

** Botulinum Toxin; R = Randomized; B = Blind; F = Fluoroscopy; AC = Active-control; NR = Non-randomized; P = Positive; N = Negative; NA = Not Applicable

Source: Hansen H, et al. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. *Pain Physician* 2012; 15:E247-E278 (18).

Table 25. *Results of randomized and observational studies of effectiveness of radiofrequency lesioning sacroiliac joint.*

Study Study Characteristics Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results			Comment
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	1 year	
CONVENTIONAL RADIOFREQUENCY NEUROTOMY									
Cohen et al (241) NR, F 8/13	77	Conventional or cooled radiofrequency from L4/5 to S3/4	NA	66.7% improvement	NA	P	P	NA	Positive study
COOLED RADIOFREQUENCY NEUROTOMY									
Cohen et al (242) R, DB, PC 11/12	Total: 28 Placebo = 14 Radiofrequency = 14	Cooled radiofrequency or Sham	Treatment group: 64% success rate Control group: 14%	Treatment group: 57% success rate Control group: 0%	Treatment group: 14% in open-label follow-up	P = RF N = Sham	P = RF N = Sham	N	Positive trial
Patel et al (243) R, DB, PC 11/12	51 (34 treatment, 17 control)	Cooled radiofrequency versus Sham	Treatment group: 47% success rate Control group: 12%	Treatment group: 38% success rate Control group: NA	NA	P = RF N = Sham	P = RF N = Sham	NA	Positive trial
PULSED RADIOFREQUENCY NEUROTOMY									
Vallejo et al (244) NR 10/13	126	Pulsed radiofrequency	55%	32% had between 17 and 32 weeks worth of relief	NA	P = RF N = Sham	P = RF N = Sham	P = RF N = Sham	Positive study

R = Randomized; DB = Double-Blind; PC = Placebo Control; F = Fluoroscopy; NR = Non-randomized; P = Positive; N = Negative; NA = Not Applicable; RF = Radiofrequency

Source: Hansen H, et al. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. *Pain Physician* 2012; 15:E247-E278 (18).

Consequently, since there is good evidence for diagnostic sacroiliac joint injections, these should be covered. Further, if appropriately performed 4 times a year and the patient shows significant improvement, therapeutic sacroiliac joint injections also should be covered based on the evolving evidence. Even though there are no randomized trials showing the effectiveness of sacroiliac joint injections, there is strong evidence from observational studies.

In reference to therapeutic sacroiliac joint interventions, there was limited evidence for intraarticular injections, pulsed radiofrequency neurotomy, and conventional radiofrequency neurotomy. However, there was fair evidence for cooled radiofrequency neurotomy based on 2 randomized trials.

Indications

- Common indications for diagnostic and therapeutic sacroiliac joint interventions 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
  - Contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate nonsteroidal anti-inflammatory drugs
  - For therapeutic sacroiliac joint interventions with intraarticular injections or radiofrequency neurotomy, the joint should have been positive utilizing controlled diagnostic blocks.

Frequency of Interventions

- In the diagnostic phase, a patient may receive 2 injections at intervals of no sooner than one week or, preferably, 2 weeks.

- In the therapeutic phase (after the stabilization is completed), the frequency should be 2 months or longer between each injection, provided that no less than 50% relief is obtained for 2 months. However, if the neural blockade is applied for different regions, it can be performed at intervals of no sooner than one week or, preferably, 2 weeks for most type of blocks. The therapeutic frequency must remain at 2 months for each region.

- In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary, judging by the medical necessity criteria, and these should be limited to a maximum of 4 times for local anesthetic and steroid blocks for a period of one-year.

Percutaneous and Endoscopic Laminectomy and Disc Decompression Procedures

In reference to percutaneous disc decompression procedures, Cigna states the following:

> **Cigna does not cover a percutaneous or endoscopic laminectomy or disc decompression procedure, including but not limited to the following, because it is considered experimental, investigational or unproven (this list may not be all-inclusive):**
>
> - automated percutaneous lumbar discectomy (APLD)/automated percutaneous nucleotomy (CPT code 62287, HCPS codes C2614)
> - Coblation® Nucleoplasty™, disc nucleoplasty, decompression nucleoplasty plasma disc decompression (CPT code 62287)
> - endoscopic anterior spinal surgery/Yeung endoscopic spinal system (YESS)/percutaneous endoscopic diskectomy (PELD)/arthroscopic microdiscectomy, selective endoscopic discectomy (SED) (CPT code 62287)
> - endoscopic disc decompression, ablation, or annular modulation using the DiscFX™ System (CPT code 62287)
> - percutaneous laminotomy/laminectomy, percutaneous spinal decompression (e.g., mild® procedure) (CPT codes 22899, 64999, 0274T, 0275T)
> - percutaneous laser discectomy /decompression, laser-assisted disc decompression (LADD) (CPT code 62287)

It appears that percutaneous adhesiolysis is not covered by this policy.

Adhesiolysis was developed as a means of removing epidural scarring leading directly or indirectly to compression, inflammation, swelling, or a decreased nutritional supply of nerve roots. Adhesiolysis utilizes a number of modalities in the effort to break up epidural scarring, including the use of a wire-bound catheter for mechanical adhesiolysis, placement of the catheter in the ventro-lateral aspect of the epidural space at the site of the exiting nerve root, and the use of high volumes of injectate, including local anesthetics and saline, either hypertonic or isotonic, along with steroids.

Helm et al (19), in a systematic review, evaluated the effectiveness of percutaneous adhesiolysis in the treatment of refractory low back and leg pain due to post lumbar surgery syndrome or spinal stenosis. The severity of risks and adverse advents associated with percutaneous adhesiolysis were also evaluated. They concluded that there is fair evidence that percutaneous adhesiolysis is effective in relieving low back and/or leg pain due to post lumbar surgery syndrome or spinal stenosis.

Tables 26 and 27 illustrate the results of studies of percutaneous adhesiolysis in the management of chronic low back pain (245-250).

Table 26. *Results of randomized studies on the efficacy of percutaneous adhesiolysis in post lumbar surgery syndrome.*

Study Study Characteristics Methodological Quality Scoring	Participants	Pain Relief and Function	Results at 12 months	Comments
Manchikanti et al (245) RA, AC 10/12	120 60 adhesiolysis 60 caudal epidural steroid	73% of adhesiolysis group had >50% relief at 12 months; 12% of caudal group did. 3-4 adhesiolysis procedures/year	P	High quality study showing good evidence of effectiveness.
Heavner et al (246) RA, AC 10/12	59	83% of the patients showed significant improvement compared to 49% at 3 months, 43% at 6 months, and 49% at 12 months.	P	High quality study with positive results.
Manchikanti et al (247) RA, AC 10/12	75 25 caudal epidural steroid injection 25 one-day adhesiolysis with normal saline 25 one-day adhesiolysis with hypertonic saline	72% of hypertonic saline and 60% of normal saline patients had >50% relief at 12 months, versus 0% of caudal injections.	P	High quality study with positive results.
Veihelmann et al (248) RA, AC 7/12	47 one –day adhesiolysis 52 physical therapy	There was a significant decrease in VAS and Oswestry scores at 1, 3, 6, and 12 months. 28 adhesiolysis patients were able to decrease Gerbershagen grade compared to 2 PT patients.	p	Results undetermined.

RA = Randomized; AC = Active Control; NR = Non-Randomized; PR = Prospective; RE = Retrospective; P = Positive; N = Negative

Source: Helm S II, et al. Percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome and spinal stenosis: A systematic review. *Pain Physician* 2012; 15:E435-E462 (19).

Table 27. *Results of randomized and observational studies on the effectiveness of percutaneous adhesiolysis in lumbar spinal stenosis.*

Study Study Characteristics Methodological Quality Scoring	Participants	Pain relief and Function	Results at 12 months	Comments.
Manchikanti et al (249) R, AC 10/12	25 adhesiolysis; 25 caudal epidural steroid	76% of adhesiolysis patients had > 50% relief at 12 months; 4% of the epidural group did. Average of 3-4 adhesiolysis procedures per year	P	High quality study with positive results.
Park et al (250) PR 7/13	66, all had adhesiolysis	66% had improvement at 6 months	NA	Moderate quality study with positive results.

R = Randomized; AC = Active Control; PR = Prospective; P = Positive; N = Negative

Source: Helm S II, et al. Percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome and spinal stenosis: A systematic review. *Pain Physician* 2012; 15:E435-E462 (19).

Evidence

Helm et al (19), in a systematic review, evaluated the effectiveness of percutaneous adhesiolysis in the treatment of refractory low back and leg pain due to post lumbar surgery syndrome or spinal stenosis. The severity of risks and adverse events associated with percutaneous adhesiolysis were also evaluated. They concluded that there is fair evidence that percutaneous adhesiolysis is effective in relieving low back and/or leg pain due to post lumbar surgery syndrome or spinal stenosis.

Indications

- Chronic low back and/or lower extremity pain resulting from:
  - failed back surgery syndrome/epidural fibrosis
  - spinal stenosis
  - disc herniation/spondylolisthesis and degenerative disc disease refractory to all other treatments.
- 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.

Frequency of Interventions

- The number of procedures should be limited to:
  - with a 3-day protocol, 2 interventions per year or
  - with a one-day protocol, a maximum of 4 interventions per year.

SUMMARY

We request that appropriate guidelines be utilized to provide proper care to Cigna policy holders. The policy is not only inappropriate, but it is also prescriptive and proscriptive instead of patient-oriented and evidence-based.

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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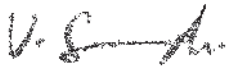

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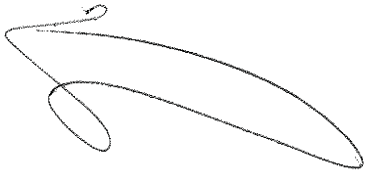

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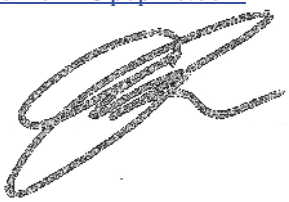

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