American Society of Interventional Pain Physicians

"The Voice of Interventional Pain Management"

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Re: Minimally Invasive Treatment of Back and Neck Pain
Effective Date: 7-15-2013
(Coverage Policy Number 0139)

Dr. Kessel:

Thank you for updating Cigna Medical Coverage Policy Number 0139 effective 7/15/2013: Minimally Invasive Treatment of Back and Neck Pain. We thank you for updating the policy from 7/15/2012. We also applaud you for using the most current literature in the majority of the policy; however, there are multiple deficiencies in this policy because parts of it are verbatim as the previous one with no differences in coverage, despite our previous request dated October 19, 2012 (1). The policy is inconsistent with its own literature search and the findings obtained from the literature. Further, it is internally inconsistent with indications, medical necessity, and procedural and diagnostic coding systems. Consequently, we are very much concerned with this development and its implications for noncoverage beyond one year and coverage for many indicated conditions, even within one year.

Consequently, on behalf of the American Society of Interventional Pain Physicians (ASIPP) and 51 affiliated state societies and multiple other organizations, we would like to present objections to the policy and request an appropriate review of the literature (even though it has been performed to a great extent). A policy based upon incorporating an appropriate review and use of the literature will lead to appropriate coverage and better health outcomes.

Based on the appropriate analysis of available evidence utilizing Institute of Medicine (IOM) principles for preparing systematic reviews and guidelines as shown in the Cigna policy itself, there is good to fair evidence for multiple procedures described in this policy. ASIPP guidelines, which rigorously apply IOM standards, have concluded fair to good evidence for 52% of therapeutic interventions and 61% of diagnostic interventions (2). Our comments are limited to epidural injections, but also include percutaneous adhesiolysis; facet joint interventions including therapeutic facet joint injections; nerve blocks; radiofrequency neurotomy; and sacroiliac joint interventions. As Cigna has discussed extensively in the policy, we would like you to reconsider the evidence, add the evidence that was published after the publication of this coverage policy, and withdraw the present policy or modify it to cover a multitude of the procedures for therapeutic management beyond the initial period after establishment of the appropriate diagnosis.

To summarize our request, which will be described in detail and accompanied with related evidence, please approve the following:

1. The restriction of one-year treatment and reimbursement for interventional techniques should be removed.

    - Chronic pain lasts beyond one-year, thus this restriction is inappropriate. The entire practice of interventional pain management supported by literature illustrates that repeated treatments of interventional techniques are necessary, except for very few techniques such as spinal cord stimulation. Currently the evidence is good to fair for most interventional techniques when they are repeated.

    - Interventional techniques must be approved appropriately with 2 blocks in the diagnostic phase followed by 4 per region in the therapeutic phase; and for ablative procedures or radiofrequency neurotomy, 2 procedures per year are indicated with at least 2½ to 3 months of documented relief with each procedure for epidurals and nerve blocks and 5-6 months for radiofrequency.

2. Coverage for epidural injections should include spinal stenosis, post surgery syndrome, and discogenic pain without facet or sacroiliac joint pain.

    - The evidence is fair for spinal stenosis, post surgery syndrome, and discogenic pain in the cervical, thoracic, and lumbar spine.

3. Among the facet joint interventions, therapeutic facet joint nerve blocks have the best evidence available. Consequently, these should be approved. The evidence ranges from fair to good in the cervical, thoracic, and lumbosacral spine.

4. Percutaneous adhesiolysis utilizing a catheter must be added to the coverage criteria. This procedure has fair evidence for lumbar post surgery syndrome, lumbar spinal stenosis, and intractable and recalcitrant pain secondary to other disorders in the lumbar spine.

5. The policy should establish guidance on qualifications of the professionals who provide these services.

6. The policy should also provide guidance on the requirements for a facility where the procedures are performed.

Detailed discussion of each item shown above along with evidence synthesis is shown below.

1.0 BACKGROUND INFORMATION:

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

ASIPP is represented by state societies in all the states including Puerto Rico. Multiple members from various other organizations such as North American Neuromodulation Society (NANS), American Society of Anesthesiologists (ASA), American Academy of Physical Medicine and Rehabilitation (AAPMR), and International Spine Intervention Society (ISIS) are also extremely interested in the modification of this policy as we are requesting.

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 (3).

Interventional pain management techniques are minimally invasive procedures including percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves and some surgical techniques such as laser or endoscopic diskectomy, intrathecal infusion pumps and spinal cord stimulators for the diagnosis and management of chronic, persistent or intractable pain (4).

2.0 EVIDENCE SYNTHESIS

Even though the Cigna policy has extensively discussed the evidence synthesis, but has not incorporated evidence into recommendations. As you well know, there has been a growing emphasis on evidence synthesis and development of guidelines based on systematic reviews with the IOM re-engineering its definition of clinical guidelines in 2011 (5). Accordingly, the new definition emphasizes that "clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternate care options." Thus, the new definition departs from a 1990 IOM report, which defined guidelines as, "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (6).

The new definition provides a clear distinction between the term "clinical practice guideline" and other forms of clinical guidance derived from widely disparate development processes, such as consensus statement, expert advice, and appropriate use criteria. In addition, the new definition also underscores systematic review and both benefits and harms assessment as essential components of clinical practice guidelines. While any group of individuals can designate itself as an evidence-based medicine, comparative effectiveness research or guideline group, they may reach different conclusions based on various interests (5). However, IOM provided guidance for trustworthy guidelines, noting that they should be:

1. Based on a systematic review of the existing evidence
2. Developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups
3. Considerate of important patient subgroups and patient preferences, as appropriate
4. Based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest

5. Clear in their explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations
6. Reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.

Appropriately developed guidelines must incorporate validity, reliability, reproducibility, clinical applicability, flexibility, clarity, development through a multidisciplinary process, scheduled reviews, and documentation (7). When appropriately applied, rigorously developed guidelines have the potential to reduce undesirable practice variation, reduce the use of services that are of minimal or questionable value, increase utilization of services that are effective, but underused, and target services to those populations most likely to benefit.

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

In preparing guidelines and systematic reviews, it is essential to apply methodologic quality or validity assessment of all included manuscripts, rather than utilizing individual opinions. Further, this process should be transparent and available to the public. As the policy shows for cervical epidural injections, Hayes guidelines are used as a reference. These are not available openly to the public. They are not scrutinized or peer-reviewed. Similarly, Milliman guidelines follow the same principles competing for business from industry, as well as the provider community. To subscribe to these guidelines, it costs a physician tens of thousands of dollars. Consequently, any conclusions recommended by organizations without transparency and free availability and publication in peer-reviewed journals, that lack listing on the Agency for Healthcare Research and Quality (AHRQ) National Guidelines Clearinghouse (NGC), and that are expensive to review, must be abandoned.

In grading the overall strength of evidence for an intervention, the United States Preventive Services Task Force (USPSTF) (8) has established 2 systems which classify the strength as good, fair, and limited or poor, and Grade I to III (Tables 1 and 2).

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

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

Adapted and modified from methods developed by U.S. Preventive Services Task Force (8).

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

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

Adapted from the Agency for Healthcare Research and Quality, U.S. Preventive Services Task Force (8).

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

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

3.0 COMPARISON OF EVIDENCE SYNTHESIS IN CIGNA POLICY

The Cigna medical coverage policy quotes numerous manuscripts rather extensively. We are pleased that almost all the manuscripts have been quoted from ASIPP guidelines and extensively discussed; however, the major weight has been given to outdated and inadequately performed guidance. Some of the guidelines such as American College of Occupational and Environmental Medicine (ACOEM) guidelines and American Pain Society (APS) guidelines are not published on NGC, which have been given an extremely high weight.

Guidelines can be developed with funding provided by the industry in favor or against one of them. ASIPP guidelines though developed by interventional pain physicians included all specialties with a multidisciplinary involvement with a strict criteria to adherence have shown rather humbling results with only 52% of therapeutic interventions receiving a grade of fair to good recommendation.

4.0 PROFESSIONAL QUALIFICATIONS

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

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

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

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

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

5.0 FACILITY REQUIREMENTS

- These procedures must be performed in a Medicare-approved hospital outpatient department, ambulatory surgery center, or a physician office equipped with proper facility including appropriately trained personnel with training in resuscitation and all required emergency equipment.

6.0 IMAGING

The use of imaging guidance, particularly fluoroscopy or computed tomography, with the use of injectable radiopaque contrast material has been shown to enhance the accuracy and safety of needle placement. Use of imaging guidance with the use of injectable radiopaque contrast material for epidural injections and percutaneous adhesiolysis with proper needle placement for facet joint interventions and sacroiliac joint interventions has been shown to enhance the accuracy and safety of needle placement for all epidural injection procedures. Consequently, imaging guidance must be mandated except when it is contraindicated. Consequently, imaging guidance must be mandated except when it is contraindicated.

7.0 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 two weeks

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
- minimum interval of two months between injection sessions

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 two months.

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 experimental, investigational or unproven.

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

7.1 Evidence Synthesis

Epidural injections are provided with multiple approaches for both the regions (cervical, thoracic; lumbosacral) with caudal approach for lumbosacral region, interlaminar approaches for cervical/thoracic and lumbosacral regions; and lumbosacral transforaminal epidural injections and rarely performed cervical and thoracic transforaminal epidural injections. Epidural injections may also be performed with or without steroids. Recent evidence illustrates significant or even better effectiveness without steroids (2,9).

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 (2,10-14). Overall, the evidence has been good to fair – superior compared to previous evaluations.

7.1.1 Caudal Epidural Injections

Parr et al (10) 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 3 illustrates the studies utilized in managing lumbar disc herniation or radiculitis with caudal epidural injection (15-19).

In this evaluation, only randomized trials were included. Even though Iversen et al's study (15) 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 (15) also included multiple flaws in their inclusion criteria and analysis, along with lack of fluoroscopy (20).

Table 3. *Results of randomized trials 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	
Manchikanti et al (17) RA, 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 (18) RA, 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 (19) RA, 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.
Iversen et al (15) RA, 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.
Murakibhavi & Khemka (16) RA, AC, B 7/12	Total = 102	Conservative management or caudal epidural steroid injections	Group A = 32% Group B = 92%	Group A = 24% Group B = 86%	NA	P	P	NA	Positive short-term results in a moderate quality study

RA = Randomized; PC = Placebo Control; AC = Active Control; UL = Ultrasound; F = Fluoroscopy; B = Blind; P = Positive; N = Negative; NA = Not Applicable; U = Unclear; SI = Significant Improvement

Source: Parr AT, Manchikanti L, Hameed H, Conn A, Manchikanti KN, Benyamin RM, Diwan S, Singh V, Abdi S. Caudal epidural injections in the management of chronic low back pain: A systematic appraisal of the literature. *Pain Physician* 2012; 15:E159-E198 (10).

Parr et al (10) showed the evidence of randomized and observational studies in managing low back pain of post surgery syndrome as illustrated in Table 4 (21-23). 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 4. *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 (21) RA, 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.
Yousef et al (23) RA, 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 group.
Revel et al (22) RA, 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.

RA = Randomized; AC = Active Control; B = Blind; F = Fluoroscopy; P = Positive; NA = Not Applicable

Source: Parr AT, Manchikanti L, Hameed H, Conn A, Manchikanti KN, Benyamin RM, Diwan S, Singh V, Abdi S. Caudal epidural injections in the management of chronic low back pain: A systematic appraisal of the literature. *Pain Physician* 2012; 15:E159-E198 (10).

Parr et al (10) showed the evidence of randomized and observational studies in managing low back pain of spinal stenosis as illustrated in Table 5 (24). 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 5. *Results of randomized trials 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 (24) RA, 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.

RA = Randomized; AC = Active Control; F = Fluoroscopy; P = Positive

Source: Parr AT, Manchikanti L, Hameed H, Conn A, Manchikanti KN, Benyamin RM, Diwan S, Singh V, Abdi S. Caudal epidural injections in the management of chronic low back pain: A systematic appraisal of the literature. *Pain Physician* 2012; 15:E159-E198 (10).

Parr et al (10) showed the evidence of randomized trials and observational studies in managing low back pain of discogenic pain as illustrated in Table 6 (25). 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 6. *Results of randomized trials 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 (25) RA, 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.

R = Randomized; AC = Active Control; F = Fluoroscopy; P = Positive

Source: Parr AT, Manchikanti L, Hameed H, Conn A, Manchikanti KN, Benyamin RM, Diwan S, Singh V, Abdi S. Caudal epidural injections in the management of chronic low back pain: A systematic appraisal of the literature. *Pain Physician* 2012; 15:E159-E198 (10).

7.1.2 Lumbar Interlaminar Epidural Injections

Lumbar interlaminar epidural injections have been studied for disc herniation, spinal stenosis, and discogenic pain (11). The results were evaluated appropriately utilizing methodologic quality assessment criteria of randomized and observational studies.

Benyamin et al (11) 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 7 shows the effectiveness of lumbar interlaminar epidural injections in managing disc herniation and radiculitis (18,26-36).

Table 7. *Results of randomized trials 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 (26,27) 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 (28) 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 (29) 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
Kim & Brown (30) 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 (31) 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
Ackerman & Ahmad (18) RA, 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.

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	
Dilke et al (32) R, PC, B 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
Pirbudak et al (33) RA, AC, B 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 (34) RA, PC, B 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 (35) RA, PC, B 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.
Wilson-MacDonald et al (36) RA, AC, B 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

* = ketamine group; ** = amitriptyline; RA = Randomized; PC = Placebo control; AC = Active-control; F = Fluoroscopy; B = Blind; IL = Interlaminar; TF = Transforaminal; SI = Significant improvement; NSI – No significant improvement; P = positive; N = negative; NA = Not applicable; U = Unclear

Source: Benyamin RM, Manchikanti L, Parr AT, Diwan SA, Singh V, Falco FJE, Datta S, Abdi S, Hirsch JA. The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. *Pain Physician* 2012; 15:E363-E404 (11).

Benyamin et al (11) 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 8 shows the effectiveness of lumbar interlaminar epidural injections in managing in discogenic pain (37,38).

Table 8. *Results of randomized trials 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 (37,38) RA, 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

RA = Randomized; AC = Active-control; F = Fluoroscopy; P = Positive

Source: Benyamin RM, Manchikanti L, Parr AT, Diwan SA, Singh V, Falco FJE, Datta S, Abdi S, Hirsch JA. The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. *Pain Physician* 2012; 15:E363-E404 (11).

Benyamin et al (11) 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 9 shows the effectiveness of lumbar interlaminar epidural injections in managing in spinal stenosis (28,39-43).

Table 9. *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	≥ 1 year	
Manchikanti et al (39) RA, 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 (28) RA, 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 (40) RA, 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 (41) RA, AC, PC, B 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 (42) RA, AC, B 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 (43) RA, AC, B 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

RA = Randomized; AC = Active-control; PC = Placebo controlled; B = Blind; F = Fluoroscopy; P = Positive; N = Negative; NA = Not applicable; U = Unclear; SI = Significant improvement; NSI = No significant improvement

Source: Benyamin RM, Manchikanti L, Parr AT, Diwan SA, Singh V, Falco FJE, Datta S, Abdi S, Hirsch JA. The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. *Pain Physician* 2012; 15:E363-E404 (11).

7.1.3 Lumbar Transforaminal Epidural Injections

Manchikanti et al (12) 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 10 illustrates the effectiveness of lumbar transforaminal epidural injections in managing disc herniation or radiculitis demonstrated in randomized trials (18,28,29,44-53).

Table 10. *Results of randomized trials 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	Long-Term 1 year	
Ghahreman et al (44) RA, 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 (45,46) RA, 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.
Cohen et al, 2012 (47) RA, PC, F 10/12	Total = 84 Saline group = 30 Corticosteroid = 28 Etanercept = 26	Steroids, etanercept, or saline Number of Injections: 1-2	Steroid group: 50% Etanercept group: 42% Saline group: 43%	Steroid group: 29% Etanercept group: 38% Saline group: 40%	Steroid group: NA Etanercept group: NA Saline group: NA	N	N	NA	Although this was a well conducted study, it was not a true placebo study. Even though there was no significant difference, authors concluded that epidural steroid injections may provide most short-term pain relief for some. The included patients were subacute sciatica.
Jeong et al (48) RA, 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
Riew et al (49,50) RA, 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.

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	
Ng et al (51) RA, AC 11/12	Total = 86 Bupivacaine = 43 Bupivacaine + steroid = 43	Bupivacaine only, or bupivacaine with methylprednisolone Number of injections = 1	Bupivacaine =4 7.5% Bupivacaine + steroid = 41.5%	NA	NA	P = steroids Negative = local anesthetic	NA	NA	Positive results in a small study with short-term follow-up.
Lee et al (28) RA, 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 (18) RA, 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 =1 60% Transforaminal = 83%	Caudal = 57%) Interlaminar = 60% Transforaminal = 83%	NA	P	P	NA	Relatively short-term follow-up with high volumes of injection.
Park et al (52) RA, AC 7/12	Total =106 Dexamethasone =5 3 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.
Rados et al (29) RA, 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 (53) RA, 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

RA = randomized; PC = placebo control; AC = active-control; F = Fluoroscopy; IL = interlaminar TF = transforaminal; P = positive; N = negative; NA = not applicable; U = unclear; G = ganglionic; PG = preganglionic; SI = significant improvement; VAS = visual analog scale; ODI = Oswestry Disability Index; ** = triamcinolone compared dexamethasone

Source: Manchikanti L, Buenaventura RM, Manchikanti KN, Ruan X, Gupta S, Smith HS, Christo PJ, Ward SP. Effectiveness of therapeutic lumbar transforaminal epidural steroid injections in managing lumbar spinal pain. *Pain Physician* 2012; 15:E199-E245 (12).

Manchikanti et al (12) concluded that the evidence is fair for radiculitis secondary to spinal stenosis with local anesthetic and steroids. Table 11 illustrates the effectiveness of lumbar transforaminal epidural injections in managing spinal stenosis (28,48,51,53).

Table 11. *Results of randomized trials 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 (48) RA, 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 (51) RA, 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 (28) RA, 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 (53) RA, 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.

RA = randomized; AC = active-control; P = positive; N = negative; NA = not applicable; VAS = visual analog scale; ODI = Oswestry Disability Index

Source: Manchikanti L, Buenaventura RM, Manchikanti KN, Ruan X, Gupta S, Smith HS, Christo PJ, Ward SP. Effectiveness of therapeutic lumbar transforaminal epidural steroid injections in managing lumbar spinal pain. *Pain Physician* 2012; 15:E199-E245 (12).

7.1.4 Cervical Epidural Injections

Cervical epidural injections also have been studied in multiple studies and a systematic review has been performed recently (13). There have been condition specific evaluations of cervical epidural injections. Table 12 illustrates the effectiveness of cervical interlaminar epidural injections in disc herniation and radiculitis, discogenic pain, spinal stenosis, and post surgery syndrome (54-62).

Diwan et al (13) 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 12. *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.	1 year	
DISC HERNIATION AND RADICULITIS									
Manchikanti et al (54,55) RA, 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 (56) RA, 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 (57) RA, 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 (58) RA, 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 (59,60) RA, 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 (61) RA, 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 (62) RA, AC, F 10/12	56	Local anesthetic or with Celestone	68% vs. 68%	64% vs. 71%	71% vs. 64%	P	P	P	Positive results

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

Source: Diwan SA, Manchikant L, Benyamin RM, Bryce DA, Geffert S, Hameed H, Sharma ML, Abdi S, Falco FJE. Effectiveness of cervical epidural injections in the management of chronic neck and upper extremity pain. *Pain Physician* 2012; 15:E405-E434 (13).

7.1.5 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 (14) 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 13 illustrates the studies utilized in the evaluation of thoracic interlaminar epidural injections (63).

Table 13. *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 (63)	RA, 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

RA = Randomized; AC = Active Control; F = Fluoroscopy; NRS = Numeric Rating Scale; ODI = Oswestry Disability Index

Source: Benyamin RM, Wang V, Vallejo R, Singh V, Helm S II. A systematic evaluation of thoracic interlaminar epidural injections. *Pain Physician* 2012; 15:E497-E514 (14).

7.1.6 Cost Effectiveness

The included interventional techniques herewith also have shown with favorable results in cost utility analysis with $2,200 for caudal epidural injections in the treatment of lumbar disc herniation, central spinal stenosis, post lumbar surgery syndrome, and axial or discogenic low back pain (64) (Table 14). These cost utility analysis assessments are highly favorable compared to surgical interventions or occasionally prolonged physical therapy or other rehabilitation programs. Consequently, it is expected that cost utility analysis, other approaches, and application of these procedures in other regions will yield very similar results.

Table 14. *Analysis of cost effectiveness of caudal epidural injections in managing pain and disability of disc herniation, discogenic pain, spinal stenosis, and post surgery syndrome in 480 patients.*

	Disc Herniation	Axial or Discogenic Pain	Spinal Stenosis	Post Surgery Syndrome	Total
Number of patients	120	120	100	140	480
Total number of procedures for 2 years	601	647	400	696	2344
Number of treatments for 2 years per patient (mean) ± SD	5.0 ± 2.55	5.4 ± 2.63	4.0 ± 2.57	5.0 ± 2.76	4.9 ± 2.67
Number of weeks with significant improvement for all patients in the study in weeks for 2 years	6294	7254	4305	7096	24949
Significant improvement in weeks per procedure (mean) ± SEM	9.4 ± 7.23	10.7 ± 8.25	9.7 ± 13.54	8.4 ± 6.14	9.5 ± 8.92
Number of weeks with significant improvement per patient for 2 years	52.5 ± 38.46	60.4 ± 37.71	43.1 ± 41.52	50.7 ± 38.71	52.0 ± 39.33
Total Cost ($)					
Physician	$74,761.00	$81,729.00	$45,944.00	$88,776.00	$291,210.00
Facility	$192,225.00	$216,268.00	$132,468.00	$210,168.00	$751,129.00
Total	$266,986.00	$297,997.00	$178,412.00	$298,944.00	$1,042,339.00
Cost per procedure ($)					
Physician	$124.40	$126.30	$115.10	$127.60	$124.30
Facility	$319.80	$334.30	$332.00	$302.00	$320.60
Total	$444.20	$460.60	$447.10	$429.50	$444.90
Cost per 1-week QALY ($)	$42.42	$41.08	$41.44	$42.13	$41.78
Cost per 1-year QALY ($)	$2,205.79	$2,136.18	$2,155.03	$2,190.68	$2,172.50
Cost per 2-year QALY ($)	$4,411.59	$4,272.36	$4,310.07	$4,381.37	$4,344.99
Average Total cost per patient for 2 years	$2,225.00	$2,483.00	$1,784.00	$2,135.00	$2,172.00

Source: Manchikanti L, Falco FJE, Pampati V, Cash KA, Benyamin RM, Hirsch JA. Cost utility analysis of caudal epidural injections in the treatment of lumbar disc herniation, central spinal stenosis, post lumbar surgery syndrome, and axial or discogenic low back pain. *Pain Physician* 2013; 16:E129-E143 (64).

7.1.7 Summary

As described earlier, the policy has multiple issues. Even though appropriate literature has been utilized, conclusions do not correlate with the evidence, along with the coverage decision. Consequently, as described the policy ICD-9 and 10 coding, the procedures are indicated for spinal stenosis, post surgery syndrome, and axial or discogenic without facet joint or sacroiliac joint pain (2,10-14).

7.1.8 Indications

- Chronic spinal and/or upper extremity, chest wall or lower extremity pain of at least 3 months duration which has failed to respond or poorly responded to non-interventional and non-surgical conservative management resulting from:

  - Cervical, thoracic, and lumbosacral disc herniation or radiculitis

    Cervical interlaminar epidural (evidence - good)
    Thoracic interlaminar epidural (evidence - fair)
    Lumbar interlaminar epidural (evidence – good)
    Caudal epidural (evidence – good)
    Lumbar transforaminal epidural (evidence – good)
    Cervical transforaminal epidural (no evidence – no indications)
    Thoracic transforaminal epidural (no evidence – no indications)

  - Cervical, thoracic, or lumbosacral spinal stenosis

    Cervical interlaminar epidural (evidence - fair)
    Thoracic interlaminar epidural (evidence –limited)
    Lumbar interlaminar epidural (evidence – fair)
    Caudal epidural (evidence – fair)
    Lumbar transforaminal epidural (evidence – limited)
    Cervical transforaminal epidural (no evidence – no indications)
    Thoracic transforaminal epidural (no evidence – no indications)

  - Post cervical, thoracic, or lumbar surgery syndrome

    Cervical interlaminar epidural (evidence - fair)
    Thoracic interlaminar epidural (evidence – limited)
    Lumbar interlaminar epidural (evidence – not available)
    Caudal epidural (evidence – fair)
    Lumbar transforaminal epidural (evidence – limited)
    Cervical transforaminal epidural (no evidence – no indications)
    Thoracic transforaminal epidural (no evidence – no indications)

  - Axial or discogenic pain without facet joint pathology, disc herniation, or sacroiliac joint pathology in the cervical, thoracic, and lumbosacral spine

    Cervical interlaminar epidural (evidence - fair)
    Thoracic interlaminar epidural (evidence – fair)
    Lumbar interlaminar epidural (evidence – fair)
    Caudal epidural (evidence – fair)
    Lumbar transforaminal epidural (evidence - limited)
    Cervical transforaminal epidural (no evidence – no indications)
    Thoracic transforaminal epidural (no evidence – no indications)

- Intermittent or continuous pain causing functional disability

- Contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate nonsteroidal anti-inflammatory drugs

7.1.9 Frequency and Utilization

Levels per session

1. No more than two transforaminal injections may be performed at a single setting (e.g. single level bilaterally or two levels unilaterally)
2. One caudal or lumbar interlaminar injection or cervical or thoracic epidural injection; per session and not in conjunction with a transforaminal injection.

Frequency with criteria

1. No more than 2 epidural injections may be performed in the diagnostic phase per region (cervical and thoracic is considered as one region, lumbar and sacral is considered as a separate region).
2. With documentation of at least 6 weeks of improvement with first 2 epidural injections in the diagnostic phase, therapeutic epidural injections may be performed not exceeding 4 per year with documentation of at least 2½ to 3 months of pain relief greater than 50% with documentation of improvement in functional status (therapeutic phase starts with first therapeutic injection) for repeat injections.
3. For transforaminal epidural injections, a maximum of 2 levels will be reimbursed, unilateral or one bilateral irrespective of the levels utilized and irrespective of the nerves blocked in one region.
4. If a prior epidural injection provided no relief, a second ESI is allowed following reassessment of the patient and injection technique.
5. All types of injections including epidural injections, facet joint interventions, sacroiliac joint injections, trigger point injections, are limited to 2 per region in the diagnostic phase and 4 per region, per year after the therapeutic phase is established.
    - In the diagnostic phase, multiple levels and multiple types of interventions may be provided in the same session; however, only one type of treatment will be allowed per region.
6. Steroids should not be injected no sooner than 4 weeks in the diagnostic phase and no sooner than 2½ to 3 months in therapeutic phase with limits of the dosages as described in the section on procedural requirements.

Sedation:

1. Local anesthesia or minimal to moderate conscious sedation may be appropriate options.
2. Monitored anesthesia care is recommended on rare occasions with clear documentation of the need for such sedation.

7.1.10 Documentation Requirements

Complete initial evaluation including history and physical examination.

- ♦ Physiological and functional assessment, as necessary and feasible.
- ♦ Description of indications and medical necessity, as follows:
    - Suspected organic problem.
    - Pain and disability of moderate-to-severe degree.
- ♦ No evidence of contraindications, such as severe spinal stenosis resulting in intraspinal obstruction, infection, or predominantly psychogenic pain.
- ♦ Nonresponsiveness to conservative modalities of treatment.

- ♦ Responsiveness to prior interventions with improvement in physical and functional status for repeat blocks or other interventions with appropriate consideration to the adverse effects including those of corticosteroids.

8.0 PERCUTANEOUS ADHESIOLYSIS

The policy states as follows:

OTHER PROCEDURES
Cigna does not cover ANY of the following procedures because each is considered experimental, investigational or unproven (this list may not be all-inclusive):
• devices for annular repair (e.g., Inclose™ Surgical Mesh System, Xclose™ Tissue Repair System (Anulex Technologies, Inc., Minnetonka, MN)
• endoscopic epidural adhesiolysis (CPT code 64999)
• epiduroscopy, epidural myeloscopy, epidural spinal endoscopy (CPT code 64999)
• intradiscal and/or paravertebral oxygen/ozone injection
• percutaneous epidural adhesiolysis, percutaneous epidural lysis of adhesions, Racz procedure (CPT codes 62263, 62264)

8.1 Evidence Synthesis

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 (65), 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.

Gerdesmeyer et al (66) in a randomized, multicenter, double-blind, placebo controlled trial showed efficacy of percutaneous adhesiolysis.

Tables 15 to 17 illustrate the results of studies of percutaneous adhesiolysis in the management of chronic low back pain (67-74).

Table 15. *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 (67,68) 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 82% of adhesiolysis group had significant improvement versus 5% in control group at 24 months - 6-7 procedures for 2 years.	P	High quality trial showing good evidence of effectiveness.
Heavner et al (69) 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 trial with positive results.
Manchikanti et al (70) RA, AC 10/12	75 25 caudal epidural steroid injection 25 1-day adhesiolysis with normal saline 25 1-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 trial with positive results.
Veihelmann et al (71) RA, AC 7/12	47 1 –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	Moderate quality positive study

RA = randomized; AC = active-control; P = positive

Source: Helm S II, Benyamin RM, Chopra P, Deer TR, Justiz R. 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 (65).

Table 16. *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 (72,73) RA, AC 10/12	25 adhesiolysis; 25 caudal epidural steroid Observational phase: 70 patients	76% of adhesiolysis patients had >50% relief at 12 months; 4% of the epidural group did. In a 2-year follow-up of 70 patients in observational phase Average of 3-4 adhesiolysis procedures per year. 71% of patients showed significant improvement at the end of 2 years – 5-6 procedures per 2 years	P	High quality study with positive results.
Park et al (74) PR 7/13	66, all had adhesiolysis	66% had improvement at 6 months	NA	Moderate quality study with positive results.

RA = randomized; AC = active-control; PR = prospective; P = positive; NA = not available

Source: Helm S II, Benyamin RM, Chopra P, Deer TR, Justiz R. 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 (65).

Table 17. *Studies on the effectiveness of percutaneous adhesiolysis in lumbar radiculopathy.*

Study Study Characteristics Methodological Quality Scoring	Participants	Outcome Measures	Pain Relief and Function	Results at 12 mos.	Comments
Gerdesmeyer et al, 2013, (66) RA, PC	Placebo = 44 Intervention = 44	VAS, ODI, >50% improvement of VAS and ODI	**At 6 months:** • >50% improvement in ODI Placebo = 4 of 37 (11%) Intervention group = 31 of 42 (74%) • >50% improvement in VAS Placebo= 14 of 36 (39%) Intervention group = 32 of 42 (76%) **At one year:** • >50% improvement in ODI Placebo = 9 of 26 (35 Intervention group = 28 of 31 (90%) • >50% improvement in VAS Placebo = 18 of 26 (69% Intervention group =29 of 31 (94%)	Positive results for adhesiolysis group	First randomized, multicenter, double-blind, placebo controlled, trial showing effectiveness in lumbar radiculopathy

RA = Randomized; PC = Placebo Control; VAS = visual analog scale; ODI = Oswestry Disability Index

8.2 Cost Effectiveness

The included interventional techniques herewith also have shown with favorable results in cost utility analysis with $2,650 per one year of quality-adjusted life year for percutaneous adhesiolysis in the treatment of post lumbar surgery syndrome and lumbar central spinal stenosis as shown in Table 18 (75). These cost utility analysis assessments are highly favorable compared to surgical interventions or occasionally prolonged physical therapy or other rehabilitation programs.

Table 18. *Analysis of cost effectiveness of percutaneous adhesiolysis injections in managing pain and disability of lumbar spinal stenosis and post surgery syndrome.*

	Spinal Stenosis	Post Surgery Syndrome	Total
Number of patients	70	60	130
Total number of procedures for 2 years	397	385	782
Number of treatments for 2 years per patient (mean) ± SD	5.7 + 2.73	6.4 ± 2.32	6.0 + 2.56
Number of weeks with significant improvement for all patients in the study in weeks	4979	4704	9686
Significant improvement in weeks per procedure (mean) ± SEM	13.2 + 12.6	11.7 ± 2.97	12.5 + 9.47
Total cost ($)			
Physician	$87,028	$83,112	$170,140
Facility	$166,891	$156,529	$323,420
Total	$253,919	$239,641	$493,560
Cost per procedure ($)			
Physician	$219.21	$215.88	$217.57
Facility	$420.38	$406.56	$413.58
Total	$639.59	$622.44	$631.15
Cost for 1-week improvement in quality of life ($)	$51.00	$ 50.94	$50.96
Cost for 1-year improvement in quality of life ($)	$2,652	$2,649	$2,650
Cost for 2-year improvement in quality of life ($)	$5,304	$5,298	$5,299
Average total cost patient in two years	$3,627	$3,994	$3,797

$ is adjusted to 2012

Source: Manchikanti L, Helm II S, Pampati V, Racz GB. Cost utility analysis of percutaneous adhesiolysis in managing pain of post lumbar surgery syndrome and lumbar central spinal stenosis. *Pain Pract* submitted for publication; 2013 (75).

8.3 Indications

- Chronic low back and/or lower extremity pain resulting from:
  - Failed back surgery syndrome/epidural fibrosis (evidence – fair)
  - Spinal stenosis (evidence – fair)
  - Disc herniation/spondylolisthesis and degenerative disc disease refractory to all other treatments (evidence – fair)
- Duration of pain of at least 6 months.
- Intermittent or continuous pain causing functional disability.
- Failure to respond or poor response to noninterventional and non-surgical conservative management and fluoroscopically-directed epidural injections

8.4 Frequency

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

8.5 Documentation Requirements

Complete initial evaluation including history and physical examination.

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

9.0 FACET JOINT INTERVENTIONS

The policy states 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)

***Note: A facet joint injection performed on the same side at the same level subsequent to a diagnostic injection is considered to be therapeutic; see policy statement below on coverage of therapeutic facet joint injection.**

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.

ABLATIVE TREATMENT
Cigna covers initial percutaneous 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 percutaneous 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 experimental, investigational or unproven.

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)
- Endoscopic radiofrequency denervation/endoscopic dorsal ramus rhizotomy (CPT code 64999)
- Cryoablation/cryoneurolysis/cryodenervation (CPT code 64999)
- Chemical ablation (e.g., alcohol, phenol, glycerol) (CPT codes 64633-64636)
- Laser ablation (CPT code 64999)
- Sacroiliac (SI) joint nerve ablation by any method (CPT code 64640)

9.1 Evidence Synthesis

Facet joint interventions are provided for diagnostic as well as therapeutic purposes. Diagnostic facet joint interventions include facet joint nerve blocks in the cervical, thoracic, and lumbosacral spine. Therapeutic facet joint interventions include intraarticular injections, facet joint nerve blocks, and radiofrequency neurotomy.

9.1.1 Diagnostic Facet Joint Injections

9.1.1.1 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 (76,77). 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 (78-81). Facet joints have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity (76,82-92). 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 (76,77,82,93-99).

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 (76,80,82,93,100). Construct validity of facet joint blocks is important to eliminate placebo effect as the source of confounding results and to secure true-positive results (76,82,83,92). 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 (2,76,82,100-102).

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 (76,88,103-107).

The systematic review by Falco et al (76) of diagnostic cervical facet joint nerve blocks, utilizing 9 studies (83-88,90-92) 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 (89).

The systematic review by Falco et al (76) showed false-positive rates with a single block of 27% to 63% with CIs ranging from 15% to 78% (Table 19) (83-88,90-92,108,109).

Table 19. *Data of prevalence and false-positive rates of pain of cervical facet joint origin based on controlled diagnostic blocks with 75%-100% pain relief as criterion standard.*

Study	% Relief Used	Methodological Criteria Score	Number of Subjects	Prevalence Estimates with 95% Confidence Intervals	False-Positive Rate with 95% Confidence Intervals
Yin and Bogduk (83)	> 80%	9/12	143	55%* (95% CI, 38%, 62%)	NA
Manchukonda et al (84)	> 80%	9/12	251 of 500	39% (95% CI, 32%, 45%)	45% (95% CI 37%, 52%)
Manchikanti et al (85)	> 80%	9/12	255 of 500	55% (95% CI, 49%, 61%)	63% (95% CI 54%, 72%)
Manchikanti et al (86)	> 80%	9/12	120	67% (95% CI 58% , 75%)	63% (95% CI 48% , 78%)
Manchikanti et al (87)	> 75%	9/12	106	60% (95% CI, 50%, 70%)	40% (95% CI, 34%, 46%)
Speldewinde et al (88)	> 90%	9/12	97	36% (95% CI, 27%, 45%)	NA
Barnsley et al (91)	> 90%	9/12	50	54% (95% CI, 40%, 68%)	NA
Lord et al (90)	> 90%	9/12	68	60% (95% CI, 46%, 73%)	NA
Barnsley et al (92)	> 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; 15:E807-E838 (76).

Further, Rubinstein and van Tulder (82), 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 (2,76,101,110,111), 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.

9.1.1.2 Diagnostic Thoracic Facet Joint Interventions

Atluri et al (112), 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 20 shows data of the prevalence of thoracic joint pain by controlled diagnostic blocks (84,85,113).

Table 20. *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 (113)	≥ 80%	10/12	46	48% (95% CI; 34%-62%)	58% (95% CI; 38%-78%)
Manchikanti et al (85)	> 80%	10/12	72	42% (95% CI; 30%-53%)	55% (95% CI; 38%-78%)
Manchukonda et al (84)	> 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, Singh V, Datta S, Geffert S, Sehgal N, Falco FJE. Diagnostic accuracy of thoracic facet joint nerve blocks: An update of the assessment of evidence. *Pain Physician* 2012; 15:E483-E496 (112).

9.1.1.3 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 (2,114). 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 (2,78,114-120). Facet joints have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity (2,84-86,100,114,121-124). 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 (2,114,125,126).

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 (2,100,114). Construct validity of facet joint blocks is important to eliminate placebo effect as the source of confounding results and to secure true-positive results (2,100,114,127). 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 (100-102,127,128).

The specificity of the effect of lumbar facet joint blocks was demonstrated in controlled trials (129,130). Provocation response of facet joint pain was shown to be unreliable in one study (131).

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 (131-134). 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 (105,135) and lack of influence of psychological factors on the validity of controlled lumbar diagnostic local anesthetic blocks of facet joints was demonstrated (103,136). Other variables including prior opioid exposure were also evaluated (104,137,138).

Data of prevalence of lumbar facet joint by diagnostic blocks is illustrated in Table 21 (84-86,122,123,124,133,139-145).

Based on the systematic review by Falco et al (146), diagnostic lumbar facet joint nerve blocks, utilizing 13 studies (84-86,122,123,124,133,139-145) 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 21. *Data of prevalence of lumbar facet joint pain by diagnostic blocks with controlled blocks with ≥75%-100% relief.*

Study	Methodological Criteria Score	Number of Subjects	Prevalence Estimates with 95% Confidence Intervals	False-Positive Rate with 95% Confidence Intervals
Manchikanti et al, 2001 (139)	11/12	120	40% (31%–49%)	47% (35%-59%)
Manchikanti et al, 1999 (122)	11/12	120	45% (36% - 54%)	41% (29% - 53%)
Manchikanti et al, 2000 (140)	12/12	180	36% (29% - 43%)	25% (21% - 39%)
Laslett et al 2004, 2006 (141,142)	12/12	151	24.2%	NA
Manchikanti et al, 2003 (123)	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 (86)	11/12	120	40% (31% - 49%)	30% (20% - 40%)
Manchikanti et al, 2004 (85)	11/12	397	31% (27% - 36%)	27% (22% - 32%)
Manchukonda et al, 2007 (84)	11/12	303	27% (22% - 33%)	45% (36% - 53%)
Manchikanti et al, 2007 (124)	11/12	117	16% (9%–23%)	49% (39%–59%)
Manchikanti et al, 2010 (133)	11/12	491	31% (26% - 35%)	42% (35% - 50%)
DePalma et al, 2011 (143)	11/12	156	31% (24% - 38%)	NA
Manchikanti et al, 2001 (144)	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 (145)	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 the systematic assessment of the diagnostic accuracy of lumbar facet joint nerve blocks. *Pain Physician* 2012; 15:E869-E907 (146).

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 (2,110,111,114,146), 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.

9.1.1.4 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 (76).

Atluri et al (112), 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 (146).

9.1.1.5 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
  - 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
  - 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

9.1.1.6 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.

9.1.2 Therapeutic 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.

9.1.2.1 Therapeutic Cervical Facet Joint Interventions

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

Tables 22 to 24 illustrate the results of cervical facet joint interventions (93,94,96,97,147-154).

Table 22. *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 (93,94,147)	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 (154)	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; 15:E839-E868 (77).

Table 23. *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 (148)	RA, AC	6/12	200	SPP	SPP	SPP	U	U
Barnsley et al, 1994 (149)	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; 15:E839-E868 (77).

At present, in the literature, one well performed randomized double-blind trial has been published in 2 publications (93,94) with one-year follow-up and 2-year follow-up. There is also one prospective evaluation (95). Falco et al (77) reviewed the evidence from all the available publications on medial branch blocks and included a randomized trial and observational study in their evaluation (95).

Table 24. *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 (96)	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 (97)	P	7/12	46	NA	NA	Mean VAS change 4.6 ± 1.8	*P*	*P*
Macvicar et al, 2012 (150)	P	7/12	104	NA	74% & 61%	74% & 61%	*P*	*P*
Speldewinde, 2011 (151)	P	7/12	130	NA	76%	76%	*P*	*P*
Govind et al, 2003 (152)	P	7/12	49	NA	88%	88%	*P*	*P*
Cohen et al, 2007 (153)	R	7/12	92	NA	55%	55%	*P*	*P*

RA = randomized; DB = double-blind; P = prospective; R = retrospective; VAS = Visual Analog Scale; *P* = positive; NA = not available

Source: Falco FJE, et al. Systematic review of therapeutic effectiveness of cervical facet joint interventions: An update. *Pain Physician* 2012; 15:E839-E868 (77).

With reference to radiofrequency neurotomy: for cervical radiofrequency neurotomy there was only one randomized trial which met inclusion criteria (97), and 3 observational studies (97-99).

9.1.2.2 Therapeutic Thoracic Facet Joint Interventions

Manchikanti et al (155), 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 25 illustrates the results of randomized and observational studies of thoracic facet joint interventions (156-161).

Table 25. *Results of randomized and observational studies of thoracic facet joint interventions (medial branch blocks and radiofrequency neurotomy).*

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 (156-158) 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 (159) 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 (160) P 8/13	40 patients with thoracic pain were evaluated	N/A	N/A	64%	N/A	*P*
Speldewinde (161) 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, Atluri S, Singh V, Geffert S, Sehgal N, Falco FJE. An update of evaluation of therapeutic thoracic facet joint interventions. *Pain Physician* 2012; 15:E463-E481 (155).

9.1.2.3 Therapeutic Lumbar Facet Joint Interventions

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

Based on the available evidence (2,162), therapeutic intraarticular facet joint injections are not recommended.

Tables 26 to 28 illustrate the results of therapeutic studies (125,126,163-168,176-180).

Table 26. *Results of randomized trials of effectiveness of 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	
Nath et al, 2008 (125) 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 or active	NA	Positive short and long-term
van Kleef et al, 1999 (168) 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 or active	*P* for radiofrequency N for sham or active	Positive short and long-term results
Civelek et al, 2012 (163) 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 (164) 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*	NA	NA	Positive short-term results with dual blocks
Tekin et al, 2007 (165) 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 or active	*P* for radiofrequency N for sham or active	Positive short and long-term results
van Wijk et al, 2005 (166) 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 (167) RA, AC 10/12	45	CRF	NA	60%	NA	NA	P	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 the effectiveness of therapeutic lumbar facet joint interventions. *Pain Physician* 2012; 15:E909-E953 (162).

Table 27. *Results of randomized trials of 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 (163) 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 (126,176,177) 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 (178) 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; LA = Local Anesthetic; P=Positive; NA = Not Applicable

Source: Falco FJE, et al. An update of the effectiveness of therapeutic lumbar facet joint interventions. *Pain Physician* 2012; 15:E909-E953 (162).

Table 28. *Results of randomized trials of 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	
Carette et al 1991 (179) RA, DB, PC or AC Single block confirmed 11/12	11/12	97	Methylprednisolone acetate =49 Isotonic saline =48 patients	33% vs. 42%	22% vs. 10%	N	N	NA	Negative results
Fuchs et al 2005 (180) R, DB, AC 8/12	8/12	60	Hyaluronic acid versus glucocorticoid with 6 injections.	Significant proportion of patients	Significant proportion of patients	U	U	NA	Undetermined

RA = Randomized; DB = Double-Blind; AC = Active Control; PC = Placebo Control; R = Retrospective; *P*=Positive; N=Negative; NA= Not Applicable; U = Undetermined; NA = Not available

Source: Falco FJE, et al. An update of the effectiveness of therapeutic lumbar facet joint interventions. *Pain Physician* 2012; 15:E909-E953 (162).

9.1.3 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.

9.1.4 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 (77), 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 (155), 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 (162), 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.

9.1.5 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
  - 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
  - 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

9.1.6 Frequency and Utilization

Levels per session: No more than 2 joints may be allowed per region at a single setting either bilateral or unilateral for any of the facet joint interventions.

Frequency with criteria:

1. Two diagnostic injections are allowed per region irrespective of the joints injected with maximum of 2 joints allowable per session per region.

2. No more than 4 therapeutic facet joint nerve blocks per year are reimbursable with 2 levels per region, per session after the appropriate documentation of 80% improvement with diagnostic blocks for the duration of the local anesthetic, and with a total relief and improvement of at least 50% of 6 weeks (including $\geq$ 80% relief and $\geq$ 50% relief).

3. Two radiofrequency neurotomies per year involving 2 joints per region per session may be performed 2 times a year with appropriate documentation of relief with dual MBBs and 5 to 6 months of pain relief and functional improvement after a session.

4. Intraarticular injections may benefit some patients with appropriate documentation of indications and medical necessity.

5. All types of injections including diagnostic facet joint blocks, epidural injections, sacroiliac joint injections and trigger point injections, are limited to 2 per region in the diagnostic phase, and 4 per region, per year, after the therapeutic phase is established. For radiofrequency neurotomy, therapeutic procedures are limited to 2 per year.

6. In the diagnostic phase, multiple levels and multiple types of interventions may be provided in the same session; however, only one type of treatment will be allowed for reimbursement. Further, the limits of 2 diagnostic interventions per region apply for all types of interventions for that region and for all joints.

   Exceptions apply to cervical and thoracic region in which a patient suffers with facet joint pain in the cervical spine and disc related pain requiring epidural injections or another type of treatment in the thoracic spine or vice versa may be treated with both interventions; however, limits of 2 for radiofrequency and 4 for other injections is applicable.

Sedation:
Local anesthesia or minimal to moderate conscious sedation may be appropriate options. For the diagnostic injections it is recommended that opioids be avoided.

9.1.7 Documentation Requirements

- Complete initial evaluation including history and physical examination;
- Physiological and functional assessment, as necessary and feasible;
- Description of indications and medical necessity, as follows:
  - Suspected organic problem;
  - Pain and disability of moderate-to-severe degree;
  - No evidence of contraindications such as severe spinal stenosis resulting in intraspinal obstruction, infection, or predominantly psychogenic pain;
  - Nonresponsiveness to conservative modalities of treatment;
  - Repeating interventions only upon return of pain and deterioration in functional status; and/or
  - Responsiveness to prior interventions with improvement in physical and functional status for repeat blocks or other interventions.
- Document the total amount of injectate for all medications used, **not** to exceed 0.5 to 1 mL per facet joint or medial branch nerve for diagnostic blocks.
- The standard of care for all facet joint/nerve injections requires that these procedures be performed under fluoroscopic- or CT-guided imaging. An image (plain radiograph with conventional film or specialized paper) documenting the needle position must be obtained and retained whenever a substance is injected.

10.0 SACROILIAC (SI) JOINT INJECTIONS

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 SI joint injection (CPT code 27096) for the diagnosis or treatment of acute, subacute, or chronic back pain or radicular syndromes not associated with localized SI joint pathology confirmed on imaging studies because it is considered experimental, investigational, or unproven.**
>
> **Cigna does not cover ultrasound guidance (76942) for SI joint injection for any indication because it is considered experimental, investigational, or unproven**

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

10.1 Diagnostic Sacroiliac Joint Interventions

Simopoulos et al (181), 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 29 illustrates data of the prevalence of sacroiliac joint pain by controlled diagnostic blocks (139,182-189).

Table 29. *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
Manchikanti et al (139)	80%	9/11	20	10%	22%
Laslett et al (182)	80%	8/11	43/48	25.6%	NA
Maigne et al (183)	75%	8/11	54	18.5%	20%
DePalma et al (184,185)	75%	8/11	156	18.2%	NA
DePalma et al (186)	75%	8/11	27	18.2%	NA
DePalma et al (187)	75%	8/11	170	18.2%	NA
Liliang et al (189)	75%	8/11	52	40.4%	26%

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 (181).

10.2 Therapeutic Sacroiliac Joint Interventions

Hansen et al (190), in a systematic review, evaluated the clinical utility of sacroiliac joint interventions.

Tables 30 to 32 illustrate the results of studies of therapeutic sacroiliac joint interventions (191-201).

Table 30. *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 (191) 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 (192) 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 (193) 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 (194) 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, Manchikanti L, Simopoulous TT, Christo PJ, Gupta S, Smith HS, Hameed H, Cohen SP. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. *Pain Physician* 2012; 15:E247-E278 (190).

Table 31. *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 (195) 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 (196) R, AC, F 12/12	39 patients Botox Group (n=20) Steroid Group (n=19)	Number of injections= 1	Botox = 88.2% vs. Steroid = 26.7%	NA	NA	N = steroids P** = local anesthetic	NA	NA	Positive for Botox
Luukkainen et al (197) 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 (194) 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, Manchikanti L, Simopoulous TT, Christo PJ, Gupta S, Smith HS, Hameed H, Cohen SP. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. *Pain Physician* 2012; 15:E247-E278 (190).

Table 32. *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 (198) 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 (199) 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 (200) 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 (201) 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, Manchikanti L, Simopoulous TT, Christo PJ, Gupta S, Smith HS, Hameed H, Cohen SP. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. *Pain Physician* 2012; 15:E247-E278 (190).

10.3 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
  - 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
  - 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, the joint should have been positive utilizing controlled diagnostic blocks.

10.4 Frequency

- In the diagnostic phase, a patient may receive 2 injections at intervals of no sooner than 2 weeks or preferably 4 weeks.
- In the therapeutic phase (after the stabilization is completed), the frequency should be 3 months or longer between each injection, provided that no less than 50% relief is obtained for 2½ to 3 months. However, if the neural blockade is applied for different regions, it can be performed at intervals of no sooner than 2 weeks or preferably 4 weeks for most type of blocks. The therapeutic frequency must remain at 3 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; per region with significant improvement at 50% or greater pain relief and improvement in functional status lasting for 6 weeks. Control diagnostic blocks with relief of at least 75% to 80% during the concordant phase followed by at least 6 weeks or total relief with 2 diagnostic blocks or 50% or greater for 6 weeks.

10.5 Documentation Requirements

- Complete initial evaluation including history and physical examination;
- Physiological and functional assessment, as necessary and feasible;
- Description of indications and medical necessity, as follows:
  - Suspected organic problem;
  - Pain and disability of moderate-to-severe degree;
  - No evidence of contraindications such as severe spinal stenosis resulting in intraspinal obstruction, infection, or predominantly psychogenic pain;
  - Nonresponsiveness to conservative modalities of treatment;
  - Repeating interventions only upon return of pain and deterioration in functional status; and/or
  - Responsiveness to prior interventions with improvement in physical and functional status for repeat blocks or other interventions.
- Document the total amount of injection for all medication used, not to exceed 2 to 3 mL per sacroiliac joint for diagnostic blocks.
- The standard of care for all sacroiliac joint injections requires that these procedures be performed under fluoroscopic or CT guided imaging. An image (plain radiographic conventional film or specialized paper) documenting the needle position must be obtained and retained whenever a substance is injected.

11.0 SUMMARY:

We request the appropriate guidelines be utilized to provide proper care to Cigna policyholders. The present policy which looks extremely well written on the surface is inappropriate in that it has not utilized the evidence synthesized and it is prescriptive and proscriptive instead of patient oriented and evidence-based.

Once again, we would like to thank you on behalf of interventional pain management community for the opportunity to present our views. If you have any further questions, please feel free to contact us.

12.0 REFERENCES

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