Kentucky Society of Interventional Pain Physicians

" The Voice of Interventional Pain Management "

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Re: WellCare Authorization Rules – CoreCare National
Musculoskeletal Management: Pain Management Criteria

Dr. Schafer:

On behalf of the Kentucky Society of Interventional Pain Physicians (KSIPP), we would like to thank you for providing us with authorization rules for interventional pain management.

Kentucky Society of Interventional Pain Physicians (KSIPP) is a component society of American Society of Interventional Pain Physicians (ASIPP). ASIPP is a not-for-profit professional organization comprised of over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate, and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 7,000 appropriately trained and qualified physicians practicing interventional pain management in the United States.

Interventional pain management is defined as the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing sub acute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment (1).

Interventional pain management techniques are minimally invasive procedures, including percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic diskectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain (2).

Interventional pain management (09) also has been provided a mandatory membership to Carrier Advisory Committees (CACs) in each state in the United States (3).

ASIPP has been on the forefront developing evidence-based assessments and also evidence-based guidelines (4). ASIPP members have invested substantial resources in conducting randomized trials.

Our efforts are not only limited to interventional pain management but also in developing opioid guidelines (5,6) to curb the overuse, abuse, and at the same time maintain the access to the patients who need them.

If we understand correctly, you are stating that many services performed in office and ambulatory surgery center (ASC) settings can be performed without an authorization. We appreciate this very much so.

The document appears to be well done and well researched. We have the following comments:

1. CPT 27096 - SACROILIAC JOINT INJECTION

The indications and medical necessity are acceptable along with the limitations. The only change we would request is sacroiliac joint injections may be administered on 2 occasions during the diagnostic phase. These should be followed by limit of 4 therapeutic sacroiliac joint injections per year (4,7,8).

The second comment relates to the region being treated. May be this should be clarified that lumbar is considered as the same region, whereas cervical and thoracic are considered as separate regions.

We also are concerned about the limitations of more than 3 treatment sessions per anatomic area for 6 months which may result in 6 per year. This may be changed to 2 treatments in the diagnostic phase or early phase followed by 4 sessions or treatments per year in the therapeutic phase thereafter. This will essentially reduce some of the abuses and will limit the treatments to 4 per year rather than 6.

2. CPT 62263, 62264 - PERCUTANEOUS LYSIS OF EPIDURAL ADHESIONS

It appears that CoreCare is considering this as an experimental procedure, however in contrast to this there is much literature provided showing its effectiveness. CPT 62263 is performed rarely, 62264 is very commonly performed.

As you are well aware, percutaneous adhesiolysis has been a subject of multiple assessments including systematic reviews. Clinical effectiveness was evaluated in multiple systematic reviews, health technology assessments, and guidelines (9-20). Helm et al (13) concluded that the indicated level of evidence is fair for short- and long-term relief for percutaneous adhesiolysis in post lumbar surgery syndrome and spinal stenosis. Even though Chou et al (14) showed negative evidence, their flawed methodology has been criticized (15). Inappropriate evaluations by Spectrum also provided inaccurate conclusions (19). These were also contradicted (20). ACOEM guidelines were also performed inappropriately (16). These were repudiated (17).

In the systematic review by Helm et al (13), 3 randomized trials (21-25) and 2 observational studies (26,27) met inclusion criteria for percutaneous adhesiolysis of post surgery syndrome and spinal stenosis (3).

Table 1 shows description of randomized and observational studies of percutaneous adhesiolysis in post lumbar surgery syndrome and spinal stenosis.

Table 1. *Study characteristics of randomized and observational studies of percutaneous adhesiolysis in post lumbar surgery syndrome and spinal stenosis.*

Reference, Year	Diagnosis	Number of Patients Selection Criteria	Control/ Comparator	Outcome Measures	Time of Measurements	Results	Strengths/ Weakness	Methodological Quality Assessment
RANDOMIZED								
Manchikanti et al 2009 (21)	Post lumbar surgery syndrome 45% of the caudal group and 38% of the adhesiolysis group had a prior fusion.	Inclusion: History of lumbar spine surgery at least 6 months prior to enrollment; >18 years of age; history of low back and/or leg pain after surgery; no facet pain; failure to respond to conservative therapy, including epidurals. Exclusion: >400 mg/day morphine equivalent use; uncontrolled psychiatric disorders	60 patients had a caudal epidural steroid injection with local anesthetic, steroid and normal saline 60 patients had a 1 day adhesiolysis procedure with hypertonic saline. Repeat injection was done after at least 3 months based upon results of prior injection.	NRS, ODI, Employment status, opioid intake. A significant reduction was 50% for NRS and 40% for ODI.	3, 6 and 12 months	73% of adhesiolysis patients had >50% relief at 12 months; 12% of the epidural group did. 77% of the adhesiolysis patients had >40% reduction in ODI at 12 months; 13% of the epidural group did. The duration of relief was 11-13 weeks for adhesiolysis and 5-9 weeks for epidural. No difference between relief of back or leg pain. Adhesiolysis group received 3-4 injections per year	Strengths: High quality RCT with active comparator group showing that adhesiolysis is effective in treating low back and leg pain from post lumbar surgery syndrome. Effectiveness rather than efficacy study. Weaknesses: Preliminary report with 50 patients; high number of epidural patients who were unblinded	10/12
Heavner et al 1999 (22)	Low back and leg pain	59 patients Low back and unilateral pain below the knee unresponsive to conservative treatment and with a filling defect on epidurogram. 24 patients withdrew before the injection series was completed.	Adhesiolysis with hypertonic saline and hyaluronidase (17 patients); normal saline with hyaluronidase (15 patients); Hypertonic saline without hyaluronidase (17 patients); and normal saline without hyaluronidase. (10 patients)	VAS, MPQ VAS rated mild (0-29), moderate (30-54) or severe (55-100) Improvement was a 10 point change in VAS.	1, 3, 6, 12 months	No difference in outcomes regardless of whether hypertonic or normal saline was used or whether or not hyaluronidase was used. Between 33% and 100% of patients had improvement at each follow up period ~2/3 of patients required more than one treatment in 12 months. Mean time to repeat treatment was 70 days.	Moderate quality study showing that neither the use of hypertonic saline nor hyaluronidase influenced the outcome of adhesiolysis. Weakness: Improvement was 10 points on 1-100 VAS, not the current 30 points. ~30% of patients withdrew. Facet disease was not ruled out	10/12
Manchikanti et al 2009 (23)	Spinal stenosis	50 patients Inclusion: lumbar spinal stenosis with radicular pain > 6 months' duration; Age>50; failure to respond to conservative therapy or epidural steroid injections. Exclusion: Previous lumbar surgery; foraminal stenosis; opioid abuse; uncontrolled psychiatric disorders.	25 patients had a caudal epidural steroid injection with local anesthetic, steroid and normal saline 25 patients had a 1 day adhesiolysis procedure with hypertonic saline.	NRS, ODI, Employment status, opioid intake. A significant reduction was 50% for NRS and 40% for ODI.	3, 6 and 12 months	76% of adhesiolysis patients had >50% relief at 12 months; 4% of the epidural group did. 80% of the adhesiolysis patients had >40% reduction in ODI at 12 months; 0% of the epidural group did. The duration of relief was 12.3 weeks for adhesiolysis and 3.2 weeks for epidural. Adhesiolysis group received 3-4 injections per year	Strengths: High quality RCT with active comparator group showing that adhesiolysis is effective in treating refractory leg pain from central spinal stenosis. Effectiveness rather than efficacy study. Weaknesses: Preliminary report with 50 patients; high number of epidural patients who were unblinded	10/12

Reference, Year	Diagnosis	Number of Patients Selection Criteria	Control/ Comparator	Outcome Measures	Time of Measurements	Results	Strengths/ Weakness	Methodological Quality Assessment
Manchikanti et al 2004 (24)	Low back and leg pain Approximately 70% of participants had previous lumbar surgery.	75 patients Inclusion 18-65 years with >2 year history of low back pain and minimum VAS of 6. No facet disease. Failure to respond to epidural injections. Exclusion: large disc herniation, cauda equine syndrome, lumbar surgery in the last 6 months, drug addiction, uncontrolled psychological disorders	25 patients with caudal epidural; 25 patients with adhesiolysis procedure using normal saline; 25 patients with adhesiolysis procedure using 10% hypertonic saline. Co-interventions included analgesics and exercise. Unblinding occurred after 3 months.	VAS, ODI, work status, opioid intake, ROM and psychological evaluation using P-3. Significant pain relief was >50% relief.	3, 6, 12 months	Mean reduction of VAS at 12 months was 1.2 for epidural group, 3.6 for normal saline and 4.2 for hypertonic saline. Average duration of >50% relief with one procedure was 0% for epidural group, 3.6 months for normal saline group and 5.4 months for hypertonic group. 0% of epidural group had >50% relief at 12 months, 60% and 72% of normal saline and hypertonic groups had >50% relief at 12 months.	Strengths: High quality RCT showing that adhesiolysis provides significant relief regardless of whether normal saline or hypertonic saline is used. Weaknesses: Repeat procedures allowed based upon response to previous procedures, rather than examining one injection only.	10/12
Veihelmann et al 2006 (25)	Low back and leg pain, specifically excluding stenosis	99 patients with chronic low back pain and sciatica. Location of pain corresponded to imaging findings. Patients had failed PT, injections and medication. Exclusion were spinal stenosis, rheumatological disease and malignancy. 5 PT and 8 adhesiolysis patients had discectomy.	1-day adhesiolysis(47 patients) versus physical therapy (52 patients) Patients could cross over at 3 months; 12 switched from PT to adhesiolysis	VAS for back and leg pain. ODI, Gerbershagen score	3, 6 and 12 months	Significant pain relief at 12 months in adhesiolysis group, with >4 points and >60% improvement in VAS and with a 50% decrease in ODI. Reduction in VAS and ODI at 3 months statistically significant between PT and adhesiolysis. 12 patients in PT group switched to adhesiolysis at 6 months. 13 were lost to follow up or had surgery; only 27 PT patients were followed up at 6, 12 months.	Strengths: Moderate quality RCT showing that adhesiolysis is more effective in treating refractory low back, and leg pain from fibrosis than conservative treatment. Active comparator group; careful attention to catheter location; prospective RCT Weakness: high dropout rate from PT group.	7/12
OBSERVATIONAL								
Gerdesmeyer et al 2005 (26)	Radiculopathy. Etiology not specified	61 patients Chronic radiculopathy	3 day adhesiolysis protocol	ODI McNab score	6 months	ODI improved from 67 to 19 at three months and 28 at six months. Prior to intervention, 61 patients rated their pain moderate or bad; at 6 months, 33 were excellent or good while 22 were moderate or bad	Strengths: Prospective evaluation Outcome parameter Weakness: Mixture of multiple etiologies No control group	7/13

Reference, Year	Diagnosis	Number of Patients Selection Criteria	Control/ Comparator	Outcome Measures	Time of Measurements	Results	Strengths/ Weakness	Methodological Quality Assessment
Park et al 2011 (27)	Spinal Stenosis	66 patients with central spinal stenosis as determined by dural sac cross sectional area.. Exclusion criteria were foraminal stenosis, spondylolisthesis, previous surgery or multilevel stenosis.	1 day adhesiolysis procedure with hypertonic saline; no comparator Concurrent therapies after the procedure included NSAIDs. Opioids were provided a necessary after two weeks. Non responsive patients received epidural steroid injections.	5 point patient satisfaction scale. Patients divided into responder (No pain, much pain, slightly improved) versus non-responders (no change, worse pain.)	2 weeks, 6 months.	66% of patients had improvement at 6 months. 2 patients had surgery. Response did not depend upon severity of spinal stenosis. 17 patients had no pain relief despite no filling defect after the procedure.	Strengths: Moderate quality observational study showing effectiveness of adhesiolysis in treating refractory pain due to central spinal stenosis. Patients limited to localized central stenosis. Rigorous observational study design. Weakness: Response based upon patient report of improvement, with no measure of amount of improvement. No comparator group.	7/13

VAS = visual analog scale; MPQ = McGill Pain Questionnaire; NRS = Numeric Rating Scale; ODI = Oswestry Disability Index; ROM – range of motion; RCT – randomized controlled trial; P-3=Pain Patient Profile; PT = physical therapy; SI =sacroiliac; NSAIDs= Non-Steroidal Anti-Inflammatory Drugs

Adapted from Helm S II, et al. Percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome and spinal stenosis: A systematic review. *Pain Physician* 2012; 15:E405-E432 (13).

Table 2 shows the analysis of the results of randomized studies on the efficacy of percutaneous adhesiolysis in post lumbar surgery syndrome.

Table 2. *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 (21)	RA, AC	10/12	120 60 adhesiolysis 60 caudal epidural steroid	73% of adhesiolysis group had >50% relief at 12 months; 12% of caudal group did. 3-4 adhesiolysis procedures/year	P	High quality study showing good evidence of effectiveness.
Heavner et al (22)	RA, AC	10/12	59	83% of the patients showed significant improvement compared to 49% of the patients at 3 months, 43% of the patients at 6 months, and 49% of the patients at 12 months.	P	High quality study with positive results.
Manchikanti et al (24)	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 study with positive results.
Veihelmann et al (25)	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	Results undetermined.

RA = randomized; AC = active-control; NR = non-randomized; PR = prospective; RE = retrospective. P = positive; N = negative

Adapted from Helm S II, et al. Percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome and spinal stenosis: A systematic review. *Pain Physician* 2012; 15:E405-E432 (13).

Finally, Table 3 shows results of randomized and observational studies on the effectiveness of percutaneous adhesiolysis in lumbar spinal stenosis.

Table 3. *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 (23)	R, AC	10/12	25 adhesiolysis; 25 caudal epidural steroid	76% of adhesiolysis patients had >50% relief at 12 months; 4% of the epidural group did. Average of 3-4 adhesiolysis procedures per year	P	High quality study with positive results
Park et al (27)	PR	7/13	66, all had adhesiolysis	66% had improvement at 6 months	NA	Moderate quality study with positive results

R = randomized; AC = active-control; PR = prospective; P = positive; N = negative

Adapted from Helm S II, et al. Percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome and spinal stenosis: A systematic review. *Pain Physician* 2012; 15:E405-E432 (13).

Consequently, Helm et al (13) concluded that based upon 4 high quality randomized controlled trials with positive results (21-24) and one moderate quality randomized trial (25) with indeterminate results using United States Preventive Services Task Force (USPSTF) criteria, the evidence was fair that adhesiolysis is effective in the treatment of chronic low back and lower extremity pain due to post lumbar surgery syndrome.

Similarly, they also concluded that based upon one high quality randomized controlled trial (23) and one moderate quality observational study (27) using USPSTF criteria, the evidence was fair that adhesiolysis was effective in the treatment of chronic low back and lower extremity pain due to spinal stenosis.

Thus, we believe that percutaneous adhesiolysis is an essential treatment in managing chronic pain of spinal origin, specifically in patients with post lumbar laminectomy syndrome and spinal stenosis, recalcitrant to other modalities including fluoroscopically directed epidural injections. The recommended medical necessity and indications are as follows:

> Chronic low back and/or lower extremity pain resulting from post surgery syndrome and spinal stenosis.

We have listed only post lumbar laminectomy syndrome and spinal stenosis as proper indications as present literature limits to these 2 conditions. Making these treatments, which is effective in a significant proportion of patients, as experimental or not effective may lead to excessive utilization of epidural injections, specifically transforaminals which may be associated with extremely high risk in post lumbar surgery syndrome patients. However, the effectiveness of epidural injections in post lumbar surgery syndrome, as well as spinal stenosis is inferior to the effectiveness in discogenic pain (28-32). Consequently, refusal of percutaneous adhesiolysis will push these patients to intrathecal infusion systems or spinal cord stimulation systems increasing the costs even much higher.

3. CPT 62287 - DECOMPRESSION PROCEDURE, PERCUTANEOUS, OF NUCLEUS PULPOSUS OF INTERVERTEBRAL DISC

This should be a covered procedure.

The primary goal of surgical treatment of a disc prolapse, protrusion, or extrusion is the relief of nerve root compression by removing the herniated nuclear material (33-35). Several alternative techniques to open discectomy and microdiscectomy include automated percutaneous laser discectomy (APLD), percutaneous lumbar laser discectomy (PLLD), mechanical disc decompression with a high rotation per minute device or DeKompressor®, and nucleoplasty. All the techniques were assessed systematically (36-39).

Automated Percutaneous Lumbar Discectomy (APLD)
APLD is performed with a pneumatically driven, suction-cutting probe in a cannula with a 2.8 mm outer diameter with removal of one to 3 grams of disc material to reduce intradiscal pressure and decompress the nerve roots (36,40-56).

Gibson and Waddell (33) in a Cochrane collaboration review indicated that the place for forms of discectomy other than traditional open discectomy is unresolved. They concluded that trials of percutaneous discectomy suggest that clinical outcomes following treatment are at best fair and certainly worse than after microdiscectomy, although the importance of patient selection is acknowledged. They concluded that there is considerable evidence that surgical discectomy provides effective clinical relief for carefully selected patients with sciatica due to lumbar disc prolapse that fails to resolve with conservative management. These authors noted that unless or until better scientific evidence is available, APLD should be regarded as a research technique.

In a technology assessment report (40), negative evidence was illustrated. The systematic review by Hirsch et al (36) utilizing a combination of randomized trials and observational studies with only one randomized trial meeting inclusion criteria for evidence synthesis (44) and with 10 observational studies meeting inclusion criteria for evidence synthesis (45-52,55,56) concluded that the indicated level of evidence is II-2 in properly selected patients with contained lumbar disc prolapse.

Of the 2 published randomized trials (41,42), Revel et al (41) met the inclusion criteria for evidence synthesis. Revel et al (41) randomized patients with sciatica caused by a disc herniation to undergo as an APLD or chemonucleolysis. The trial included 72 chemonucleolysis and 69 APLD patients of whom 43% of chemonucleolysis patients and 26% of APLD patients were considered sedentary subjects and the disc appeared degenerated more often in the chemonucleolysis group (92%) than in the APLD group (76%). The study had 32 patients withdrawing during trial as therapeutic failures. At one-year follow-up, overall success rates were 66% in the chemonucleolysis group and 37% in the APLD group.

Many aspects of the Revel et al's study (41), such as patient selection criteria, which led to poor results, have been criticized (37). The size of the disc herniation was an issue because for APLD it should not occupy more than 30% of the spinal canal, whereas in Revel et al's study (41) in 59% of APLD and 64% of chemonucleolysis patients the disc herniation covered between 25% and 50% of the spinal canal. Further, in 71% of the APLD patients and 79% of chemonucleolysis patients, the disc herniation had migrated up to 5 mm cranially or caudally to the endplate levels, considered a contraindication of APLD. Other factors included that at discography, 39% of the tested discs showed epidural leakage, 76% of the discs were severely degenerated (APLD is not effective in diffuse annular bulging), 9% had marked disc space narrowing, and 21% of patients had severe back pain, but no correlation to leg pain was made.

Multiple observational studies meeting inclusion criteria have been described in detail by Hirsch et al (36) and a summary of the results of eligible studies of APLD is provided in Table 4.

Table 4. *Summary results of eligible studies of automated percutaneous lumbar discectomy included in this systematic review.*

Study	Study Characteristics	Methodological Quality Scoring	Number of Participants	Pain Relief	Results
				> 12 mos.	Long-term > 12 mos.
Revel et al (41)	RA	70	69 APLD 72 Chemonucleolysis	37% APLD 66% Chemonucleolysis	N
Shapiro (45)	O	55	57	58%	P
Grevitt et al (46)	O	70	137 (115 remained at final follow-up interview)	72%	P
Onik et al (47)	O	68	506	75%	P
Davis et al (48)	O	59	518	85%	P
Maroon & Allen (49)	O	54	1054	85%	P
Teng et al (50)	O	71	1,582	83%	P
Bonaldi et al (51)	O	58	234	75%	P
Degobbis et al (52)	O	55	50	NA	NA
Marks (55)	O	66	103	63%	P
Bernd et al (56)	O	68	238	60%	P

RA = randomized; O = observational; P = positive; N = negative; N/A = not available.

Adapted from Hirsch JA et al. Automated percutaneous lumbar discectomy for the contained herniated lumbar disc: A systematic assessment of evidence. *Pain Physician* 2009; 12:601-620 (36).

Indications of percutaneous mechanical disc decompression include the following (4,36):

1) Unilateral leg pain greater than back pain.
2) Radicular symptoms in a specific dermatomal distribution that correlates with MRI findings.
3) Positive straight leg raising test or positive bowstring sign, or both.
4) Neurologic findings or radicular symptoms.
5) No improvement after 6 weeks of conservative therapy.
6) Imaging studies (CT, MRI, discography) indicating a subligamentous contained disc herniation.
7) Well maintained disc height of 60%.

Percutaneous discectomy is associated with risks which include nerve injury, infection, bleeding, development of spinal instability, damage to endplate, and disc space collapse.

The indicated level of evidence based on USPSTF criteria (57) is Level II-2 for short- and long-term relief for APLD (4,36).

The recommendation is 1C/strong recommendation based on Guyatt et al's (58) criteria (4,36).

Percutaneous Lumbar Laser Discectomy (PLLD)

In percutaneous lumbar laser discectomy or PLLD, laser energy is used to reduce pressure by vaporizing a small volume of the nucleus pulposus. It is hypothesized that the change in pressure between the nucleus pulposus and the peridiscal tissue causes retraction of the herniation away from the nerve root (33,37,40).

Based on the systematic review by Waddell et al (34) there is no acceptable evidence for laser discectomy. However, Singh et al (37) in a systematic review of current evidence, which included observational studies, indicated the level of evidence for PLLD as Level II-2 for short- and long-term relief. The evidence was based on multiple observational studies (59-68).

Singh et al (37) described the characteristics of multiple studies included in the evidence synthesis and the details including methodologic quality scoring, and results are illustrated in Table 5.

Table 5. *Results of percutaneous disc decompression with laser assisted disc removal.*

Study	Study Characteristics	Methodological Quality Scoring	Number of Participants	Pain Relief > 12 mos	Results
Knight & Goswami (65)	O	69	576	56%	P
Bosacco et al (59)	O	58	63	66%	P
Choy (60)	O	55	518	75%	P
Zhao et al (67)	O	80	139	82%	P
Tassi (68)	O	61	419	84%	P
Grönemeyer et al (66)	O	75	200	73%	P
Nerubay et al (61)	O	55	50	74%	P
Ascher (62)	O	50	90	74%	P
Botsford (64)	O	63	292	75%	P
Casper et al (63)	O	72	100	87%	P

O = observational; P = positive; N/A = not applicable.

Adapted from Singh V et al. Percutaneous lumbar laser disc decompression: A systematic review of current evidence. *Pain Physician* 2009; 12:573-588 (37).

No cost effectiveness studies are available for PLLD.

The indications for PLLD are the same as for APLD.

Complications of APLD include instrument failures, nerve damage, reflex sympathetic dystrophy (RSD), sigmoid artery injury, anomalous iliolumbar artery injury, spondylodiscitis, and cauda equina syndrome (69-72).

The indicated level of evidence based on USPSTF criteria (57) is II-2 for short- and long-term relief (4,37).

The recommendation based on Guyatt et al's (58) criteria is 1C/strong recommendation for PLLD (4,37).

4. CPT 62290/62291 – LUMBAR AND CERVICAL DISCOGRAPHY

We appreciate coverage for discography, however, at the present time this is not reimbursed in surgery centers. Please consider a reimbursement value for this similar to adhesiolysis procedure. Discography is reimbursed by Medicare as a hospital outpatient as follows:

If a lumbar discography procedure (62290) performed in an HOPD setting, hospitals receive $1,594.20, whereas an in-office setting receives $248.14 (15.6% of an HOPD setting), and an ASC setting receives $0 (0% of an HOPD setting) (Table 6).

We believe that discography should be a separately payable service in an ASC and office, this will in turn provide cost savings.

Table 6. *2012 Medicare facility fee schedule for various setting for discography.*

CPT	Description	Office (Overhead Fee) ($)	ASC (Facility) ($)	Hospital (Facility) ($)
62290	Lumbar Discography procedure: Needle placement	171.21	0	0
72295	L/S Discography, radiological S & I	76.93	0	1594.2
Total		**248.14**	**0**	**1594.2**
62291	Cervical/thoracic Discography procedure: Needle placement	160.32	0	0
72285	C/T Discography, radiological S & I	76.58	0	1594.2
Total		236.90	0	1594.2

5. CPT 62310 - CERVICAL OR THORACIC EPIDURAL INJECTIONS

The policy is extremely well written, however, we have the following comments: Other than herniated disc, foraminal stenosis, spinal stenosis, cervical or thoracic epidural injections are indicated in discogenic as well as post laminectomy syndrome pain.

Multiple systematic reviews of cervical epidural injections have shown significant evidence-based on blind and fluoroscopically directed epidural injections (4,13,73,74). The following table illustrates the results of randomized trials of fluoroscopic cervical interlaminar epidural injections in managing disc herniation, axial or discogenic pain, spinal stenosis, and cervical post surgery syndrome. The results were positive for disc herniation or radiculitis; facet joint pain; spinal stenosis; and cervical post surgery syndrome. The systematic review of cervical epidural injections (73) also utilized blind cervical epidural studies with significant evidence as shown in Table 7.

Table 7. *Results of randomized trials of fluoroscopic cervical interlaminar epidural injections in managing disc herniation, axial or discogenic pain, spinal stenosis, and cervical postsurgery syndrome.*

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 months	Long-term relief > 6 months
Manchikanti et al 2010 (75)	RA, C, F	Group I - no steroid=35 Group II - steroid=35	77% vs. 86%	80% vs. 86%	80%	P	P
Manchikanti et al 2010 (76)	RA, C, F	Group I - no steroid=35 Group II - steroid=35	89% vs. 83%	77% vs. 74%	77% vs. 77%	P	P
Manchikanti et al 2012 (77)	RA, C, F	Group I - no steroid=30 Group II - steroid=30	77% vs. 87%	87% vs. 80%	73% vs. 70%	P	P
Manchikanti et al 2012 (78)	RA, C, F	Group I - no steroid=28 Group II - steroid=28	68% vs. 68%	64% vs. 71%	71% vs. 64%	P	P
Castagnera et al 1994 (79)	RA	Local anesthetic with steroids =14 Local anesthetic with steroids and morphine =10	79%	79%	79%	P	P
Stav et al 1993 (80)	RA	C = 17 T = 25	12% vs 68%	12% vs 68%	12% vs 68%	P	P
Pasqualucci et al 2007 (81)	RA	Single = 20 Continuous = 20 Over 180 days	NA	58% vs 74%	NA	P	NA

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

Modified and updated from Benyamin RM et al. Systematic review of the effectiveness of cervical epidurals in the management of chronic neck pain. *Pain Physician* 2009; 12:137-157 (73).

Diwan et al (82) concluded that for cervical epidurals the evidence was 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 based on USPSTF criteria.

Benyamin et al (74) concluded that the evidence based for thoracic epidural injection in treating chronic thoracic pain is considered fair and poor or limited for post thoracotomy pain, based on USPSTF criteria.

We also are concerned about the limitations of more than treatment sessions per anatomic area for 6 months. This may be changed to 2 treatments in the diagnostic phase or early phase followed by 4 sessions or treatments per year in the therapeutic phase thereafter. This will essentially reduce some of the abuses and will limit the treatments to 4 per year rather than 6.

Thus, we request that adding discogenic pain after eliminating facet joint pain and the pain of post surgery syndrome to indications along with the change of language to 2 procedures in the diagnostic phase followed by limitation of 4 procedures in the therapeutic phase per year.

6. CPT 62311 - LUMBAR INTERLAMINAR OR CAUDAL EPIDURAL INJECTION

The policy is extremely well written, however, we have the following comments: Other than herniated disc, foraminal stenosis, spinal stenosis, lumbar or caudal injections are indicated in discogenic as well as post laminectomy syndrome pain.

Under the limitation section you have provided 6 injections in the past year as a goal, however, this should be reduced to 2 injections in the diagnostic phase and no more than 4 injections per year in the therapeutic phase.

Significant evidence has been demonstrated for discogenic pain with caudal as well as lumbar interlaminar epidural injections (4,30,32,83-85).

In fact, recent systematic review by Parr et al (32) illustrated 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. Further, they showed that the evidence was fair for caudal epidural injections in managing chronic axial or discogenic pain, spinal stenosis, and post surgery syndrome, based on USPSTF criteria.

The systematic review by Benyamin et al (85) illustrated that for thoracic epidural injection in treating chronic thoracic pain the evidence is considered fair and limited for post thoracotomy pain, based on USPSTF criteria.

7. CPT 64483/64484 - TRANSFORAMINAL LUMBOSACRAL EPIDURAL INJECTIONS

The only comment for this is that once again related as the previous ones that the treatment may be approved as 2 treatments in the diagnostic phase followed by limitation of 4 therapeutic procedures per year (4,31).

8. CPT 64490-64492 - CERVICAL AND THORACIC FACET JOINT NERVE BLOCKS

The only comment we have in this is that limitation of more than 4 injections per level per year like others to keep uniform and facilitate proper treatments, these should be changed to 2 diagnostic blocks followed by 4 therapeutic injections per level, per year, as the limitation (4,86-92).

9. CPT 64493-64495 - LUMBAR OR SACRAL FACET JOINT NERVE BLOCKS

The only comment we have in this is that limitation of more than 4 injections per level per year like others to keep uniform and facilitate proper treatments, these should be changed to 2 diagnostic blocks followed by 4 therapeutic injections per level, per year, as the limitation (4,93-95).

10. CPT 64633-64636 - RADIOFREQUENCY NEUROLYSIS OF FACET JOINT NERVES OF CERVICAL/THORACIC AND LUMBAR/SACRAL REGION

This may be made somewhat stricter to avoid any type of abuse. We believe that diagnostic medial branch blocks should show at least 80% relief with ability to perform previously painful movements for duration of the local anesthetic and should require 2 controlled diagnostic blocks.

This will reduce significant abuse and overuse and lack of effectiveness of these procedures. Consequently it will reduce the cost to Medicaid.

Once again, thank you for your consideration. We appreciate proactive development of the policies. If you have any further questions, please feel free to contact us.

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