

American Society of Interventional Pain Physicians

" The Voice of Interventional Pain Management "

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RE: Percutaneous and Endoscopic Spinal Surgery: Policy # SURG.00071

Dear Dr. Briedbart:

We would like to thank you for consideration of our request for a meeting, and for the scheduled meeting on September 22. On behalf of the American Society of Interventional Pain Physicians (ASIPP), we would like to thank you for publishing the medical policy. This publication appears to have elicited significant debate and controversy and ASIPP has received a request to comment on this policy. We would to apologize for delay in submitting this response and also for a long document. The Executive Committee of ASIPP, on behalf of ASIPP board, the New York Society of Interventional Pain Physicians, and the entire membership, respectfully submit these comments to your clinical policy prior to the scheduled meeting with the New York members of ASIPP and others. The primary objective of these comments is to ensure that percutaneous techniques involving automated percutaneous lumbar discectomy (APLD) and lumbar laser discectomy with CPT code 62287 are covered appropriately and the patients insured by Empire Blue Cross Blue Shield continue to maintain access to care. However, at the present time we are not focusing on either endoscopic spinal surgery, Dekompressor technology, nucleoplasty, or *mild*® procedure in this document. However, the members presenting to you are willing to discuss these procedures also.

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

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

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

ASIPP has recently published the evidence-based guidelines for interventional techniques in the management of chronic spinal pain (3). These guidelines were based on extensive work by the authors and membership which includes 6 base documents of the guidelines (4-9) and includes multiple systematic reviews of which 4 are relevant to the present issue for consideration by Empire Blue Cross Blue Shield on percutaneous disc decompression (10-13).

We have reviewed your description of the literature which appears to be fairly comprehensive.

1.0 BACKGROUND

Chronic pain is defined as a complex and multifactorial phenomenon with pain that persists 6 months after an injury and/or beyond the usual course of an acute disease or a reasonable time for a comparable injury to heal, that is associated with chronic pathologic processes that cause continuous or intermittent pain for months or years, that may continue in the presence or absence of demonstrable pathology and may not be amenable to routine pain control methods with healing never occurring (5).

The epidemiology, scope, and impact of spinal pain are enormous (5). Pain arising from various structures of the spine constitutes the majority of the problems in the chronic pain settings. The lifetime prevalence of spinal pain has been reported as 54% to 80% (5). Further, the annual prevalence of chronic low back pain has been shown to range from 15% to 45%, with a point prevalence of 30%; any neck pain to range from 12.1% to 71.5% with annual prevalences ranging between 30% and 50%; and thoracic pain ranging from 5% to 34% (5). A significant proportion of patients suffer with disabling chronic spinal pain. Further, studies have shown that recurrence of pain is extremely common in the spine in more than 50% of the patients. In addition to this, a recent study by Freburger et al (14) reported the rising prevalence of chronic low back pain following an evaluation of North Carolina households conducted in 1992 and repeated in 2006. The results showed an increase in prevalence of chronic impairing low back pain over the 14-year interval from 3.9% in 1992 to 10.2% in 2006. Consequently, the overall prevalence of low back pain increased by 162%, an average annual increase of 11.6% across all demographic groups. Higher prevalence and disability with persistent long lasting pain has been reported in the elderly.

2.0 DEVELOPMENT OF CLINICAL EVIDENCE

The Institute of Medicine (IOM) defined clinical guidelines as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” (15). Consequently, all professionals consider clinical guidelines as constructive responses to the reality that practicing physicians require assistance for assimilating and applying the exponentially expanding, often contradictory, body of medical knowledge (16). However, it also has been stated that clinical guidelines should not attempt to supplant the independent judgment of a clinician in responding to particular clinical situations, but rather the guidelines attempt to define practices that meet the needs of most patients under most circumstances (17). Essentially, it is the objective of guidelines to enable the implementation of evidence-based medicine and comparative effectiveness research in medical decision-making with the goal of encouraging effective care (18-23). Consequently, it is expected that the **specific clinical recommendations that are contained within practice guidelines have been systematically developed by panels of experts who have access to all available evidence, have an understanding of the clinical problem, and have clinical experience with the procedure being assessed, as well as relevant research methods in order to make considered judgments.** Above all, these panels are expected to be objective and to produce recommendations that are not only up to date, but also unbiased and free from all conflicts of interest.

Sniderman and Furberg (16) described the conflicts, controversies, and limitations of the guideline process. Further, the integrity of the guideline or systematic review preparation must be maintained (24,25). The components of integrity include transparency, accountability, consistency, and independence. These factors have been shown to be lacking in many guidelines, including the ones so well embraced by many insurers – namely the APS (26-35) and ACOEM guidelines (36-40). If you look

at them carefully, you will find that there are numerous issues related to not only the above guidelines, but also the guidelines published by the Official Disability Guidelines, or ODG (41), and the guidelines by the American Society of Anesthesiologists (ASA) (42). These guidelines have shown a multitude of conflicts of interest and different conclusions based on the specific interests and advancements of various organizations and different conclusions by the same authors based on various individual guidelines. In contrast, the guidelines by the American Society of Interventional Pain Physicians incorporate a much more comprehensive view based on the extensive review of numerous interventions (18,43-68). Despite the criticism of ASIPP's guidelines by multiple organizations, they are unjustified as they are based on outdated guidelines and systematic reviews.

As you are well aware, a formal set of rules must complement medical training and common sense for clinicians so they may interpret the results of clinical research effectively (18-20,29,30,69-79). However, knowing the tools of evidence-based practice is necessary, but not completely sufficient for delivering the highest quality patient care. Clinical guidelines must incorporate not only the work of methodologists, but also clinicians who actually practice medicine and are experts in the technique being reviewed. **In fact, Congress has been concerned with this issue of appropriate representation of clinical specialists versus methodologists or physicians without expertise in the particular intervention. Basically, what we are requesting is that guideline preparers follow the rules they have established, rather than changing the rules when evidence is in favor of an intervention or is found to be opposite of their preformed conclusion(s).**

Even though the debate continues and controversies exist in the United States relating to the development and implementation of clinical guidelines, Congress eliminated the Agency for Healthcare Policy and Research (AHCPR) in 1995 soon after the development of the Acute Low Back Pain Guidelines. Over the years, AHCPR issued 19 guidelines at a cost of \$750 million (nearly \$40 million per guideline). Those guidelines were not demonstrated to have saved health care dollars and were not widely utilized, thus raising questions regarding the cost-effectiveness of governmentally developed guidelines (80,81). Further, many of the so-called mavericks and experts in guideline preparation or in the preparation of systematic reviews who may appear to be without any bias or perceived conflicts of interest, have recommended that each systematic review costs approximately \$100,000 and a guideline costs \$1 to \$3 million. While this is much less expensive than what was done by AHCPR — and what may be hoped by the new comparative effectiveness research programs — the quality of guidelines developed by independent and smaller organizations probably have better validity, but may not be suitable for many authorities. While industry conflicts of interest are stated repeatedly, conflicts of interest also extend to include the synthesis of evidence-based medicine, comparative effectiveness research, or in the preparation of clinical guidelines themselves – ranging from academic promotion apart from financial interest to preserving their own views or previous statements. Conflicts also expand to financial relationships with pharmaceutical, medical device, and biotechnology companies; financial relations with the insurance industry; professional affiliations and practice specialization with specific conflicts of interest of their own specialty; professional affiliations with practice specialization, reimbursement incentives, intellectual preconceptions, previously stated positions, professional recognition, and academic advancement; and finally, political philosophies of liberal versus conservative, for-profit and not-for-profit, etc. Even then, the issue surrounding practice guidelines' development and the evidence used in them are not limited to interventional pain management alone. As you are well aware, the Joint Cardiovascular Practice Guidelines of the American College of Cardiology (ACC) and the American Heart Association (AHA) have become important documents for guiding cardiology practice and establishing benchmarks for quality of care (82,83). An evaluation of the scientific evidence underlying these clinical practice guidelines showed that the recommendations issued were largely developed from lower levels of evidence or expert opinion. Further, the recent publication in *JAMA* indicates that very tight controls of hypertension do not provide any additional benefit (84). This may apply to various other therapies.

Our published critical assessment of APS and ACOEM guidelines has shown them to have numerous deficiencies (29,30,38-40). Both of these guidelines have many similarities, but the APS guidelines were much more comprehensive. Even then, the reassessment agreeing with Chou et al's evaluation of APS guidelines, points out multiple deficiencies and also disagrees on multiple occasions (29,30).

With reference to diagnostic interventions, the reassessment agreed with APS guidelines for sacroiliac joint blocks. However, the evidence was good for lumbar facet joint nerve blocks and was fair for provocation discography - judged by APS guidelines to be poor without appropriate evaluation.

For therapeutic interventional techniques, based on the grading of good, fair, and poor, as described by APS, the conclusions of APS and the critical assessment agreed that there is fair evidence for spinal cord stimulation in post lumbar surgery syndrome and poor evidence for lumbar intraarticular facet joint injections, lumbar interlaminar epidural injections, caudal epidural steroids for conditions other than disc herniation or radiculitis, sacroiliac joint injections, intradiscal electrothermal therapy (IDET), endoscopic adhesiolysis, and intrathecal therapy. However, the reassessment of APS guidelines for other interventional techniques, utilizing the same criteria as that of Chou et al, showed fair evidence for therapeutic lumbar facet joint nerve blocks, caudal epidural injections in disc herniation or radiculitis, percutaneous adhesiolysis in post lumbar surgery syndrome, radiofrequency neurotomy, and lumbar transforaminal epidural injections in radiculitis. Also, the reassessment illustrated that inclusion of the subsequent and latest literature changed the conclusions, with improved gradings of caudal epidural, adhesiolysis, and lumbar facet joint nerve blocks from fair to good or poor to fair.

All in all, the reassessment illustrated that the APS guidelines utilized multiple studies inappropriately and excluded many appropriate studies. The integrity assessment of the APS guidelines illustrates significant methodological failures, which raised concerns regarding transparency, accountability, consistency, and independence.

It is also of interest to note that all these rules are written by the same experts who go and perform systematic reviews. Even then they continue to change and adapt them based on the needs at the time. Many of these individuals and organizations reap financial benefits. You could state the same about ASIPP; however, while the majority of ASIPP members perform procedures, there is no direct compensation for preparing the systematic reviews or guidelines - it is a voluntary process.

The majority of the letter here focuses on appropriate evaluation of the evidence and also on the overlooked evidence, along with continuing debate.

3.0 PERCUTANEOUS DISC DECOMPRESSION

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 (85-87). 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 (88-91).

3.1 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 (88,92-108).

Gibson and Waddell (85) 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 (92), negative evidence was illustrated. The systematic review by Hirsch et al (88) utilizing a combination of randomized trials and observational studies with only one randomized trial meeting inclusion criteria for evidence synthesis (96) and with 10 observational studies meeting inclusion criteria for evidence synthesis (97-104,107,108) 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 (93,94), Revel et al (93) met the inclusion criteria for evidence synthesis. Revel et al (93) 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 (93), such as patient selection criteria, which led to poor results, have been criticized (88). 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 (93) 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 (88) and a summary of the results of eligible studies of APLD is provided in Table 1.

Table 1. 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 (93)	RA	70	69 APLD 72 Chemonucleolysis	37% APLD 66% Chemonucleolysis	N
Shapiro (97)	O	55	57	58%	P
Grevitt et al (98)	O	70	137 (115 remained at final follow-up interview)	72%	P
Onik et al (99)	O	68	506	75%	P
Davis et al (100)	O	59	518	85%	P
Maroon & Allen (101)	O	54	1054	85%	P
Teng et al (102)	O	71	1,582	83%	P
Bonaldi et al (103)	O	58	234	75%	P
Degobbis et al (104)	O	55	50	NA	NA
Marks (107)	O	66	103	63%	P
Bernd et al (108)	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 (88).

Indications of percutaneous mechanical disc decompression include the following (3,88):

- 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 (109) is Level II-2 for short- and long-term relief for APLD (3,88).

The recommendation is 1C/strong recommendation based on Guyatt et al's (110) criteria (3,88).

3.2 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 (85,89,92).

Based on the systematic review by Waddell et al (86) there is no acceptable evidence for laser discectomy. However, Singh et al (89) 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 (111-120).

Singh et al (89) described the characteristics of multiple studies included in the evidence synthesis and the details including methodologic quality scoring, and results are illustrated in Table 2.

Table 2. 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 (117)	O	69	576	56%	P
Bosacco et al (111)	O	58	63	66%	P
Choy (112)	O	55	518	75%	P
Zhao et al (119)	O	80	139	82%	P
Tassi (120)	O	61	419	84%	P
Grönemeyer et al (118)	O	75	200	73%	P
Nerubay et al (113)	O	55	50	74%	P
Ascher (114)	O	50	90	74%	P
Botsford (116)	O	63	292	75%	P
Casper et al (115)	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 (89).

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 (121-124).

The indicated level of evidence based on USPSTF criteria (109) is II-2 for short- and long-term relief (3,89).

The recommendation based on Guyatt et al's (110) criteria is 1C/strong recommendation for PLLD (3,89).

4.0 CMS COVERAGE

Centers for Medicare and Medicaid Services has approved CPT 62287 on the physician fee schedule, on hospital outpatient department fee schedule, and ambulatory surgery center fee schedules for a long period of time. However, as the instruments and equipment designed for CPT 62287 improve the indications and relative contraindications of the above techniques also improve.

In summary, we have provided you brief information on interventional pain management, interventional techniques, chronic low back pain, and up-to-date available literature on percutaneous disc decompression. We do realize some of the limitations available in the literature; however, these should be addressed in the future. Meanwhile the procedure must be approved to be performed by well-trained and qualified physicians for limited indications. A very small proportion of patients meet the strict criteria described here. This will be clinically effective and highly cost-effective. As it is very clear, open surgery may be associated with multiple problems which may be avoided with percutaneous disc decompression.

Once again we are very grateful for your meeting and consideration. If you have any further questions, please feel free to contact either ASIPP or New York Society of Interventional Pain Physicians.



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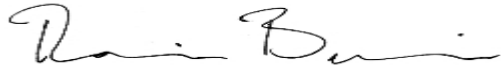
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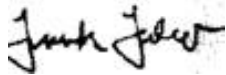
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