American Society of Interventional Pain Physicians

" The Voice of Interventional Pain Management "

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August 2, 2010

Medical Director's Office
Blue Cross and Blue Shield of Alabama
Attn: Kristi Pitts
P.O. Box 995
Birmingham, AL 35298-0001

RE: Name of Policy: Lysis of Epidural Adhesions
Policy #: 420

Dear Ms. Pitts:

On behalf of the American Society of Interventional Pain Physicians (ASIPP), we would like to thank you for publishing updated guidelines for lysis of epidural adhesions. This publication appears to have elicited significant confusion and the Society has received a request to comment on this policy. We would like to apologize for this response being submitted after the comment period due to the request being received late. The Executive Committee of ASIPP, on behalf of the ASIPP Board, the Alabama Society of Interventional Pain Physicians, and the entire membership, respectfully submit these provider comments to your clinical policy. The primary objective of these comments is to ensure that lysis of epidural adhesions are provided appropriately and that patients insured by Blue Cross Blue Shield of Alabama continue to maintain access to care.

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).

We have reviewed your description of the literature which appears to be comprehensive, especially compared to other guidelines and systematic reviews.

At this time, we are not focusing on endoscopic adhesiolysis as there is no separate code for this procedure. Please reconsider your criticism of single center studies and U.S. pain management groups. None of the criteria of methodologic quality assessment or analysis of evidence states that the studies

must not be performed in one group and must not be published in one particular journal. Please consider the evidence based on the criteria of the analysis of evidence, either utilized by Chou and Huffman (3) or the evidence criteria by United States Preventive Services Task Force (USPSTF) (4) utilized by the ASIPP guidelines. Chou and Huffman have provided all the negative evidence, despite their own positive descriptions. We will consider Chou and Huffman's criteria and utilize the evidence as described by them for lumbar epidural adhesiolysis. Chou and Huffman (3) utilized the method for grading the overall strength of the evidence for an intervention as follows (Table 1):

Table 1. *Method for grading the overall strength of the 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 two 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; two or more higher-quality trials or studies of diagnostic test accuracy with some inconsistency; at least two consistent, lower-quality trials or studies of diagnostic test accuracy, or multiple consistent observational studies with no significant methodological flaws).
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.

Source: Chou R, Huffman L. *Evaluation and Management of Low Back Pain: Evidence Review*. American Pain Society; Glenview, IL: 2009 (3). Adapted from methods developed by U.S. Preventive Services Task Force (4).

The second methodology is also developed by USPSTF, which was utilized in ASIPP guidelines (5) as follows (Table 2):

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

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 U.S. Preventive Services Task Force (USPSTF) (4).

Chou and Huffman (3) also utilized a systematic review quality rating system as follows (Table 3) and randomized controlled trials quality rating system as follows (Table 4).

Table 3. *Systematic reviews quality rating system.*

Criteria for Assessing Scientific Quality of Research Reviews*	
CRITERIA	**OPERATIONALIZATION OF CRITERIA**
1. Were the search methods reported? *Were the search methods used to find evidence (original research) on the primary questions stated?* "Yes" if the review states the databases used, date of most recent searches, and some mention of search terms.	The purpose of this index is to evaluate the scientific quality (i.e., adherence to scientific principles) of research overviews (review articles) published in the medical literature. It is not intended to measure literary quality, importance, relevance, originality, or other attributes of overviews. The index is for assessing overviews of primary ("original") research on pragmatic questions regarding causation, diagnosis, prognosis, therapy, or prevention. A research overview is a survey of research. The same principles that apply to epidemiological surveys apply to overviews: a question must be clearly specified, a target population identified and accessed, appropriate information obtained from that population in an unbiased fashion, and conclusions derived, sometimes with the help of formal statistical analysis, as is done in "meta-analyses." The fundamental difference between overviews and epidemiological studies is the unit of analysis, not the scientific issues that the questions in this index address. Since most published overviews do not include a methods section, it is difficult to answer some of the questions in the index. Base your answers, as much as possible, on information provided in the overview. If the methods that were used are reported incompletely relative to a specific question, score it as "can't tell," unless there is information in the overview to suggest either the criterion was or was not met.
2. Was the search comprehensive? *Was the search for evidence reasonably comprehensive?* "Yes" if the review searches at least 2 databases and looks at other sources (such as reference lists, hand searches, queries experts).	
3. Were the inclusion criteria reported? *Were the criteria used for deciding which studies to include in the overview reported?*	
4. Was selection bias avoided? *Was bias in the selection of studies avoided?* "Yes" if the review reports how many studies were identified by searches, numbers excluded, and gives appropriate reasons for excluding them (usually because of pre-defined inclusion/exclusion criteria).	
5. Were the validity criteria reported? *Were the criteria used for assessing the validity of the included studies reported?*	
6. Was validity assessed appropriately? *Was the validity of all the studies referred to in the text assessed using appropriate criteria (either in selecting studies for inclusion or in analyzing the studies that are cited)?* "Yes" if the review reports validity assessment and did some type of analysis with it (e.g. sensitivity analysis of results according to quality ratings, excluded low quality studies, etc.).	
7. Were the methods used to combine studies reported? *Were the methods used to combine the findings of the relevant studies (to reach a conclusion) reported?* "Yes" for studies that did qualitative analysis if there is some mention that quantitative analysis was not possible and reasons that it could not be done, or if 'best evidence' or some other grading of evidence scheme used.	
8. Were the findings combined appropriately? *Were the findings of the relevant studies combined appropriately relative to the primary question the overview addresses?* "Yes" if the review performs a test for heterogeneity before pooling, does appropriate subgroup testing, appropriate sensitivity analysis, or other such analysis.	For Question 8, if no attempt has been made to combine findings, and no statement is made regarding the inappropriateness of combining findings, check "No". If a summary (general) estimate is given anywhere in the abstract, the discussion, or the summary section of the paper, and it is not reported how that estimate was derived, mark "No" even if there is a statement regarding the limitations of combining the findings of the studies reviewed. If in doubt, mark "Can't tell."
9. Were the conclusions supported by the reported data? *Were the conclusions made by the author(s) supported by the data and/or analysis reported in the overview?*	For an overview to be scored as "Yes" in Question 9, data (not just citations) must be reported that support the main conclusions regarding the primary question(s) that the overview addresses.

10. What was the overall scientific quality of the overview? *How would you rate the scientific quality of this overview?*	The score for Question 10, the overall scientific quality, should be based on your answers to the first nine questions. The following guidelines can be used to assist with deriving a summary score: If the "Can't tell" option is used one or more times on the preceding questions, a review is likely to have minor flaws at best and it is difficult to rule out major flaws (i.e. a score of 4 or lower). If the "No" option is used on Question 2, 4, 6, or 8, the review is likely to have major flaws (i.e. a score of 3 or less, depending on the number and degree of the flaws).
Scoring:	***Each Question is scored as Yes, Partially/Can't tell or No***

Extensive Flaws		**Major Flaws**		**Minor Flaws**	**Minimal Flaws**	
1	**2**	**3**	**4**	**5**	**6**	**7**

* Operationalization of Oxman AD, Guyatt GH. Validation of an index of the quality of review articles. *J Clin Epidemiol* 1991; 44:1271-1278 (6); Adapted from Furlan AD, Clarke J, Esmail R, Sinclair S, Irvin E, Bombardier C. A critical review of reviews on the treatment of chronic low back pain. *Spine* 2001; 26:E155-E162 (7).

Source: Chou R, Huffman L. *Evaluation and Management of Low Back Pain: Evidence Review*. American Pain Society; Glenview, IL: 2009 (3).

Table 4. *Randomized controlled trials quality rating system.*

Criteria List for Methodological Quality Assessment*		
CRITERIA	**OPERATIONALIZATION OF CRITERIA**	**SCORE**
A. Was the method of randomization adequate?	A random (unpredictable) assignment sequence. An example of adequate methods is a computer generated random number table and use of sealed opaque envelopes. Methods of allocation using DOB, date of admission, hospital numbers, or alternation should not be regarded as appropriate.	Yes/No/Don't Know
B. Was the treatment allocation concealed?	Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.	Yes/No/Don't Know
C. Were the groups similar at baseline regarding the most important prognostic factors? *"Yes," if similar:* • *Age & gender* • *Description of type of pain* • *Intensity, duration, or severity of pain*	In order to receive a "yes," groups have to be similar in baseline regarding demographic factors, duration or severity of complaints, percentage of patients with neurologic symptoms, and value of main outcome measure(s).	Yes/No/Don't Know
D. Was the patient blinded to the intervention?	The reviewer determines if enough information about the blinding is given in order to score a "yes": Use the author's statement on blinding, unless there is a differing statement/reason not to (no need for explicit information on blinding).	Yes/No/Don't Know
E. Was the care provider blinded to the intervention?		Yes/No/Don't Know
F. Was the outcome assessor blinded to the intervention?		Yes/No/Don't Know
G. Were cointerventions avoided or similar?	Cointerventions should either be avoided in the trial design or similar between the index and control groups.	Yes/No/Don't Know
H. Was the compliance acceptable in all groups?	The reviewer determines if the compliance to the interventions is acceptable, based on the reported intensity, duration, number, and frequency of sessions for both the index intervention and control intervention(s).	Yes/No/Don't Know
I. Was the drop-out rate described and acceptable? *≤ 15% drop out rate is acceptable.*	The number of participants who are included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 15% and does not lead to substantial bias, a "yes" is scored.	Yes/No/Don't Know
J. Was the timing of the outcome assessment in all groups similar?	Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.	Yes/No/Don't Know
K. Did the analysis include an intention-to-treat analysis? *"Yes" if less than 5% of randomized patients excluded.*	All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values)	Yes/No/Don't Know

	irrespective of noncompliance and cointerventions.	
This list includes only the internal validity criteria (n=11) that refer to characteristics of the study that might be related to selection bias (criteria A and B), performance bias (criteria D, E, G, and H), attrition bias (criteria I and K), and detection bias (criteria F and J). The internal validity criteria should be used to define methodologic quality in the meta-analysis.		

Source: Chou R, Huffman L. *Evaluation and Management of Low Back Pain: Evidence Review*. American Pain Society; Glenview, IL: 2009 (3); adapted from methods developed by van Tulder M, Furlan AD, Bombardier C, Bouter L, the Editorial Board of the Cochrane Collaboration Back Review Group. Updated method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group. *Spine (Phila Pa 1976)* 2003; 28:1290-1299 (8).

A reassessment and a critical review of the American Pain Society (APS) clinical practice guidelines was performed recently (9).

Chou and Huffman (3) evaluated the efficacy of epidural steroid injections versus other interventions for adhesiolysis. The purpose of percutaneous epidural adhesiolysis is to minimize the deleterious effects of epidural scarring, which can physically prevent direct application of drugs to nerves and other spinal tissues; it is also used to treat chronic back pain (10,11-20). Epidural lysis of adhesions and direct deposition of corticosteroids in the spinal canal can also be achieved with a 3-dimensional view provided by epiduroscopy or spinal endoscopy (21-23).

Chou and Huffman (3) described adhesiolysis as a treatment modality for failed back surgery. They also included forceful epidural injections along with adhesiolysis with large volumes of sodium chloride solution, with or without a corticosteroid. In their search, they identified a systematic review by Trescot et al (14) which was considered and excluded based on their rating it as lower quality (13; however they included one lower quality systematic review of endoscopic division of epidural adhesions (24). They also identified 6 randomized trials (10,19,20,22,25,26).

Chou and Huffman (3) excluded one study (26) which was quasi-randomized; however, they stated that the authors of the systematic review (14) did not report quality ratings for included trials even though the ratings were, in fact, reported. Of the remaining studies, one study was rated as higher quality (10). The study by Manchikanti et al (10) compared adhesiolysis to caudal epidural steroid injection without adhesiolysis. Another study they considered was by Veihelmann et al (19) , This trial compared adhesiolysis to a poorly defined physical therapy intervention. The third trial considered was by Heavner et al (20) comparing different adhesiolysis methods.

Multiple systematic reviews and health technology assessments have evaluated the clinical effectiveness of percutaneous endoscopic adhesiolysis (11,13-15,27,28). Epter et al (28) concluded that the indicated level of evidence is I or II-1 for short- and long-term relief for percutaneous adhesiolysis in post lumbar surgery syndrome.

Recent literature search (9) yielded approximately 400 manuscripts overall . There were multiple systematic reviews, along with 5 randomized trials (10,16-20) evaluating percutaneous adhesiolysis.

Nine randomized trials were identified for percutaneous and endoscopic adhesiolysis (10,16-22,25). Of these, 7 met inclusion criteria (10,17-21,25) after exclusion of duplicates and non-randomized studies.

Table 5 illustrates the quality ratings of randomized trials of percutaneous adhesiolysis studies. A recent analysis (9) included all 5 studies. Our analysis of the quality ratings based on Chou and Huffman's (3) criteria showed significant changes on Heavner et al's (20) publication from 2 of 11 to 8 of 11 and Veihelmann et al's (19) publication from 2 of 11 to 4 of 11. It also increased the score on one of the other publications (10); however, this was already rated as higher quality by Chou and Huffman (3).

Table 5. *Quality ratings of randomized trials of percutaneous adhesiolysis studies.*

	Manchikanti et al 2009 (17)✚▲		Manchikanti et al 2009 (18) ✚▲		Heavner et al 1999 (20)*		Manchikanti et al 2004 (10)*		Veihelmann et al 2006 (19)*	
	ASIPP	APS-AAPM	ASIPP	APS-AAPM	ASIPP	APS-AAPM	ASIPP	APS-AAPM	ASIPP	APS-AAPM
Randomization	Yes	NS	Yes	NS	Yes	Don't know	Yes	Yes	Yes	No
Concealed treatment allocation	Yes	NS	Yes	NS	Yes	Don't know	Yes	Don't know	Yes	Don't know
Baseline group similarity	Yes	NS	Yes	NS	Yes	Don't know	Yes	Yes	Yes	Don't know
Patient blinded	Yes	NS	Yes	NS	Yes	Don't know	Yes	Yes	No	No
Care provider blinded	No	NS	No	NS	No	Don't know	No	No	No	No
Outcome assessor blinded	No	NS	No	NS	Yes	Don't know	Yes	Yes	No	Yes
Cointerventions avoided or similar	Yes	NS	Yes	NS	Yes	Don't know	Yes	Don't know	No	Don't know
Compliance acceptable in all groups	Yes	NS	Yes	NS	Yes	Yes	Yes	Yes	No	No
Drop-out rate described and acceptable	Yes	NS	Yes	NS	No	No	Yes	Yes	No	No
Timing of outcome assessment in all groups similar	Yes	NS	Yes	NS	Yes	Yes	Yes	Yes	Yes	Yes
Intention to treat analysis	Yes	NS	Yes	NS	No	No	Yes	Yes	No	No
Score	9/11	NS	9/11	NS	8/11	2/11	10/11	8/11	4/11	2/11

▲Not available at the time of Chou's search

✚Included in Manchikanti et al (31), but not Chou and Huffman (3)

*Included by Chou and Huffman (3) and Manchikanti et al (31)

♦Included by Chou and Huffman (3), but not Manchikanti et al (31)

NS = Not scored by APS-AAPM review

Manchikanti et al 2005 (21) was not rated by Chou and Huffman (3), instead they utilized a preliminary report

Of the multiple systematic reviews, Chou and Huffman (3) utilized only one systematic review by Trescot et al (14). They missed one systematic review (30), and another systematic review (28) was published after the search by Chou and Huffman (3). They mistakenly rated Trescot et al (14) giving it a score of 3 of 7; however, our analysis of their own numbers shows it should be 7 of 9, which is identical to our reassessment score. Similarly, for all other systematic reviews which either was not included (30) or were not published at the time of their publication, our score was 7 of 9.

The methodologic quality assessment of the criteria of systematic reviews of percutaneous adhesiolysis is illustrated in Table 6.

Table 6. *Methodologic quality assessment of systematic reviews of percutaneous and endoscopic adhesiolysis.*

	Trescot et al 2007 (14)*		Manchikanti et al 2008 (30)✚		Epter et al 2009 (28)▲✚	
	ASIPP	APS-AAPM	ASIPP	APS-AAPM	ASIPP	APS-AAPM
Search Method	Yes	Yes	Yes	NS	Yes	NS
Comprehensive	Yes	Yes	Yes	NS	Yes	NS
Inclusion Criteria	Yes	Yes	Yes	NS	Yes	NS
Bias Avoided	Yes	Yes	Yes	NS	Yes	NS
Validity Criteria	Yes	Yes	Yes	NS	Yes	NS
Validity Assessed	Yes	Partial	Yes	NS	Yes	NS
Methods for Combining Studies	No	Yes	No	NS	No	NS
Appropriately Combined	No	No	No	NS	No	NS
Conclusions Supported	Yes	Partial	Yes	NS	Yes	NS
Overall Quality	7/9	3/7	7/9	NS	7/9	NS
Corrected Score	7/9	6/9	7/9	NS	7/9	NS

▲Not available at the time of Chou's search

*Included by Chou and Huffman (3) and Manchikanti et al (31)

♦Included by Chou and Huffman (35), but not Manchikanti et al (31)

✚Included in Manchikanti et al (31), but not Chou and Huffman (35)

NS = Not scored by APS-AAPM review

Chou and Huffman (3) utilized only one appropriate study pertaining to adhesiolysis by Manchikanti et al (10), which was rated as higher quality, but was not considered of any value by them because of their inaccurate assumption that the caudal epidural group, which they considered as a placebo group, failed to respond according to their expectations. However, the manuscript illustrated significant pain relief (≥ 50%) in 33% of the patients in Group I with less than 3 months of relief. However, at 3 months and after, no significant relief was illustrated in the caudal epidural group.

The results of the effectiveness of percutaneous lysis of lumbar epidural adhesions studies published are illustrated in Table 7. Thus, it appears that there is significant evidence for percutaneous epidural adhesiolysis. Using Chou and Huffman's (3) grading of good, fair, and poor and the analysis of the included studies, it appears that there is at least fair evidence for percutaneous lumbar epidural adhesiolysis for short-term and long-term relief. However, with the inclusion of more recent studies (17,18) and systematic reviews (28,30) the evidence is good for percutaneous adhesiolysis.

Table 7. *Results of published randomized trials of percutaneous lysis of lumbar epidural adhesions.*

Study	Study Characteristics	Methodological Quality Scoring		Participants	Pain Relief				Results	
					≤ 3 mos.	3 mos.	6 mos.	12 mos.	Short-term ≤ 6 mos.	Long-term > 6 mos.
		ASIPP	APS-AAPM							
Manchikanti et al 2004 (10)	RA, DB	10/11	8/11	G1 = 25 (C) G2 = 25 (T) G3 = 25 (T)	G1 = 33% G2 = 64% G2 = 72%	G1 = 0% G2 = 64% G3 = 72%	G1 = 0% G2 = 60% G3 = 72%	G1 = 0% G2 = 60% G3 = 72%	P	P
Heavner et al 1999 (20)	RA, DB	8/11	2/11	59	83%	49%	43%	49%	P	N
Veihelmann et al 2006 (19)	RA	4/11	2/11	99	SI	SI	SI	SI	P	P
Manchikanti et al 2009 (18)	RA, DB	9/11	NS	C = 60 T = 60	90% vs 35%	90% vs 35%	85% vs 18%	73% vs 12%	P	P
Manchikanti et al 2009 (17)	RA, DB	9/11	NS	C = 25 T = 25	80% vs 28%	80% vs 28%	80% vs 12%	76% vs 4%	P	P

RA = randomized; DB = double blind; NS = not scored by APS-AAPM review; G = group; C = control; T = treatment; vs = versus; SI = significant improvement; P = positive; N = negative

Based on your policy for lysis of epidural adhesions, it appears that you also have arrived at similar conclusions to those of Chou and Huffman (3) utilizing the same criticism.

In reference to the manuscript by Manchikanti et al (10) published in 2004, the criticism of Blue Cross Blue Shield appears to be arbitrary. The protocol described the crossover; however, after the unblinding, no patient desired to undergo crossover treatment in the study. Thus, it becomes a moot point when you consider the results. A one-year follow-up was reduced to 3-month follow-up based on your own assumptions. Chronic pain patients who are not responding to interventions will not wait and endure 12 months of suffering if a treatment is not helping them. We were rather surprised that even that many patients continued in Group I without any treatment. As you can see, there were actually 2 patients in Group II and III who discontinued intervention, but there were none in Group I. Further, intention-to-treat analysis is the standard of reporting of the trials. One could say that a sensitivity analysis must be performed. At that time no sensitivity analysis was performed, however, we do not believe that that would change anything. Without intent-to-treat analysis the study results are worthless; further, the study results would show better improvement. We are happy that you have recognized that this study did show effect in patients receiving epidural steroid injections in contrast to the criticism by others. Even Chou and Huffman (3) have recognized this study as of high quality; however, their criticism was based on a misunderstanding that there was no effect in patients with steroids in Group I.

The second study by Manchikanti et al (26) included 45 patients and a convenient control group. Chou recently suggested that we should consider those types of groups, even though this study was blasted in their evaluation. Thus, evidence-based medicine proponents continue to change their minds based apparently on what needs to be said.

With regards to the review about the 2 studies with spinal stenosis and post lumbar surgery syndrome (17,18) that the study evaluating post lumbar surgery syndrome was adequate with a sample size of 60, that number should be above reproach; it is not only adequate, but it is a high number considering we take issue the paucity of literature. As for the spinal stenosis study (17), one may consider 25 patients to be a small number in each group until one recognizes that it is the first study of this subject to be performed. Both studies discussed limitations, which included a placebo group, inadequate blinding, and also the

reason for publication of preliminary results -- the paucity of literature. In essence, your document also describes what the authors have quoted as the reasons for this preliminary analysis.

Further, the argument that the number of limitations has not been clearly demonstrated for the effectiveness of epidural steroid injection is not a valid argument. There is substantial evidence of the effectiveness of epidural injections in general, and moderate evidence in post lumbar surgery syndrome and spinal stenosis —which emphasizes the necessity of approval of this procedure to be not only efficacious, but also as a cost-saving measure. Once again the issue of loss of follow-up relating to effectiveness of a technique arises. Most chronic pain patients will not continue in a treatment and are lost to follow-up if they are not responding, which further indicates the effectiveness of adhesiolysis versus epidural steroid injections. Your concern about the differential loss in follow-up, because there were no dropouts in the intervention group, may be appropriate methodologically, but it is essential to take into consideration clinical circumstances and patient values.

Waiting for the final results after 2 years, would be waiting for an additional 4 years in reality, which leads to patients suffering unnecessarily due to non-coverage policy. This same information was shared in 2000 with methodologists and insurers and will be continually repeated — even 10 years from now — until there are attitudinal changes.

In summary, even though substantial evidence is present, you continue to state that you need large, high quality, multi center controlled studies; however, none of the criteria for analysis of evidence mandate this paradigm. No specialty in medicine has been subjected to such a rigorous standard.

As you know, clinical guidelines have been defined by the Institute of Medicine (IOM) as systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances (32). Consequently, clinical guidelines are considered a constructive response to the reality that practicing physicians require assistance for assimilating and applying the exponentially expanding, often contradictory, body of medical knowledge (33). However, clinical guidelines should not attempt to supplant the independent judgment of clinicians in responding to particular clinical situations, but rather they attempt to define practices that meet the needs of most patients under most circumstances (34). **Thus, 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 the 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 must be unbiased and free from all conflicts of interest. Conflicts of interest do not relate only to industry relationships and financial conflicts, but extends as well to financial conflicts in the form of payments for preparing guidelines and systematic reviews ranging as high as $100,000 per systematic review and $1 to $2 million for guideline preparation, and also to academic interests, and the support of one's own previous opinions. These conflicts supersede the simple criticisms such as publishing from one center or in a journal such as *Pain Physician*. A careful analysis will show that *Pain Physician* is not any different from journals supported by other associations. *Pain Physician* is also listed on PubMed.

The recent analysis of APS clinical guidelines has illustrated that there was lack of integrity in preparing these guidelines, which lacks transparency, accountability, consistency, and independence (9,32).

Consequently, it is our opinion that lysis of epidural adhesions presents with good evidence even by Chou et el's criteria with appropriate analysis, and we recommend that the procedure be covered under strict criteria for limited indications of post lumbar surgery syndrome and spinal stenosis in the lumbar spine, not exceeding 4 therapeutic procedures per year.

If you have any further questions, please feel free to contact us

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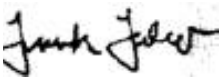

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