American Society of Anesthesiologists

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August 31, 2009

To: Noridian Administrative Services LLC Contractor Medical Director(s)
Policy Development - Medicare Part B - Drafts
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From: The American Society of Anesthesiologists

Re: Noridian proposed non-coverage (DL24471) of CPT codes 64622, 64623, 64475 and 64476 (lumbar facet blocks and denervation procedures) as portrayed at

http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=30219&lcd_version=5&show=all

The American Society of Anesthesiologists opposes adoption of Noridian's proposed non-coverage of CPT Codes 64622, 64623, 64476, 64476.

It is the opinion of the American Society of Anesthesiologists (ASA) that the proposed non-coverage of facet therapies will inappropriately obstruct access by Medicare clients to treatment options that have proven valuable to patients and have been validated as appropriate care by both evidence in the scientific literature and expert opinion. The ASA does not believe that scientific evidence exists to support this abrupt decision to effectively terminate access to this care option by patients with debilitating, chronic low back pain.

However, the ASA recognizes that some of these facet treatments have been applied improperly and luxuriantly by some practitioners, in the absence of requisite imaging direction, without sufficient physical and mental evaluation of the patient and with insufficient use of diagnostic evaluation to determine appropriate candidacy of patients for these procedures.

Further, the ASA recognizes that much of this overuse and possible abuse has been engendered by physicians who have not undergone appropriate training in interventional pain medicine, as is clear from the recent OIG report on the subject. http://oig.hhs.gov/oei/reports/oei-05-07-00200.pdf

Pain Medicine Professional Society Consensus

Consequently, the ASA has worked closely for the past two months with members of several other pain medicine professional societies (ISIS, ASRA, NASS, SIR, AAPM, AAPM&R, and ASIPP) to review the opportunities for a potential Carrier Policy that would assure the access of Noridian's Medicare clients to appropriate facet therapy. Those societies achieved consensus on many issues regarding the application of facet therapies, including:

1. That the proposed Noridian decision to rescind coverage of facet therapies is inappropriate;
2. That the concern of the OIG and Noridian in regard to facet therapy is understandable in view of the limited availability of large randomized controlled trials in the scientific literature;
3. That this lack of scientific literature reflects the relative youth of the science of interventional pain medicine rather than an inherent lack of value of the various therapies. As well, the dearth of literature support is not unique to percutaneous interventional pain treatments, but is also true of many of the more intrusive therapies used to treat back pain, such as spinal fusion. Also, we agree that the lack of RCTs is primarily a reflection of the difficult (perhaps impossible) challenge of designing ethical studies of treatment of a chronic disease (low back pain) that is protean in its pathophysiology and patient response;
4. That the experience of a large number of well-trained and experienced pain medicine specialists supports the prudent application of facet therapy as a valuable option for selected patients with chronic low back pain;
5. That these facet procedures all require the use of either fluoroscopic or CT guidance for proper performance;
6. That diagnostic blocks must be performed before proceeding with therapeutic interventions;
7. That measurement of individual and collective patient responses (outcomes) by practitioners would be of value to the individual practices and as a means of improving the understanding of the proper indications and methodology of application of the various facet therapies.

The ASA-ASRA Guidelines on the Treatment of Chronic Pain

Fortuitously, the ASA has expended significant resources over the past two years to create a new edition of the ASA Guidelines on the Treatment of Chronic Pain in conjunction with the American Society of Regional Anesthesia and Pain Medicine (ASRA) and this document, to be ratified by the ASRA Board of Directors in September and the ASA House of Delegates this October, specifically addresses facet therapies. The methodology of this process is robust, including:

1. The evaluation and grading of the scientific literature, restricted to peer-reviewed publications, by two professional epidemiologists/methodologists;
2. The review of that selected literature by a taskforce of ten experienced pain physicians, representing both academic and private practice, with resulting recommendations for guidance regarding diagnosis and therapy;
3. A review of those conclusions by an expert panel of over thirty other prominent pain physicians;
4. Open forums at two national meetings, at which these guidelines were discussed and actively debated, with particular attention to their relevance to other professional societies' guidelines;
5. A survey of the ASA and ASRA memberships to determine their degree of agreement with the proposed recommendations;
6. Finally, a survey of experts to assess the feasibility of application of the Guidelines in daily practice.

Thus, the ASA-ASRA Guidelines should be considered to be the moderate result of a reasoned and rational review of the literature, melded with expert opinion and widespread peer evaluation. This is the very definition of "evidence-based medicine".[1] Therefore, the recommendations of the ASA made in this letter concerning the Noridian coverage policies concerning facet therapies are congruent with the germane sections of these new ASA Guidelines.

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[1] Sackett DL et al. *BMJ* 1996; 312:71-72. "Evidence based medicine is not "cookbook" medicine. Because it requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice, it cannot result in slavish, cookbook approaches to individual patient care. External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision…Evidence based medicine is not restricted to randomised trials and meta-analyses."

Divergence of recommendations by professional societies

This ASA-ASRA Guideline creation process has been scrupulous, rigorous and costly. Nonetheless, it has been noted that the ASA-ASRA Guidelines vary in their conclusion from some other guidelines, as if this were evidence of some fallacy in one or the other. Instead, it is clear that these variances issue from the differences in methodology employed by each of the organizations that created the guidelines and should not be considered as proof that one or another guideline is "wrong" or "right".

For example, the American Pain Society (APS) guidelines, which do not comment on the value of many interventional pain therapies, were created with the requirement that only published randomized controlled trials could be considered as evidence. For the reasons noted above, it is no wonder that the APS guidelines do not support many interventional therapies. Thus, it would be inappropriate to consider the lack of APS support for facet therapy as judgment on the value of that therapy. Indeed, one of the APS co-chairs, Dr. John Loeser, reminded the APS taskforce repeatedly that "the absence of evidence is not the absence of efficacy". The ASA-ASRA and APS guidelines are therefore compatible, and it should be noted that one of the co-chairs of the APS guidelines taskforce, Professor Richard Rosenquist, is also the Chairman of the ASA Guidelines taskforce.

It has been noted that the Guidelines created by the American Society of Interventional Pain Physicians (ASIPP) also vary from those of the APS, and ASA-ASRA in their recommendations of indications for interventional treatment. Again, careful review elicits that these differences stem from the use of a different set of criteria for evidentiary assessment.

The primary cause of the differences in recommendations of these three guidelines is the management of literature evaluation, grading and inclusion. Since the guiding principle of evidence-based medicine is to meld expert opinion, prevailing practice and literature assessment, it is inevitable that guidelines from different sources will vary. This indicates neither a flaw in their methodology nor in the literature, but instead reflects the youthful state of the science of – in this case – invasive pain medicine. The nascent field of interventional pain medicine (barely 30 years old) should not be viewed as inadequately supported by scientific inquiry simply because of the dearth of published studies.

Thus, although the methodology of the ASA-ASRA's Guideline creation process is superb, those recommendations will of course comprise only one portion of the spectrum of recommendations that would be expected to issue from a variety of earnest scientific groups using variegated criteria in assessing an area of scientific uncertainty. So, the recommendations of APS, ASA-ASRA, and ASIPP must all be viewed as valid and it would be – at this early junction of the young disciplines of evidence-based and interventional pain medicine – an erroneous conclusion to surmise that the variation of each from the other obviates the validity of any or all.

Therefore, we recommend you look upon these guidelines in the aggregate, with an understanding of the variation in methodology that produced them, rather than compare and contrast their conclusions as opposing.

It should be noted that the representatives of the various professional pain medicine societies did have some divergence of opinion, just as the published guidelines do. For instance, the use of contrast and the level of relief necessary in diagnostic blocks to support proceeding to therapeutic intervention have been insufficiently studied in the literature. Some experts support a higher requirement of relief (e.g., 80% for two blocks vs. 50% or more relief for one) prior to qualifying a patient for RF.

However, there is no published literature that supports this stance and there is published peer-reviewed data that shows it is not correct. Moreover, even those experts admit to a false positive rate with the 80% x 2 approach that would lead to a sufficient number of falsely positive patients undergoing two MBBs and RF such that the purported savings to the health care system would be minimal or would actually see larger expenditures when the cost of a required second diagnostic block is included. As well, they have not studied the false negative rate, a potentially significant impact on the quality of care delivered to patients with facet pain. Interestingly, these same practitioners do not require a level of 80% relief after the use of RF before its re-application.

Thus, due to its potential for increased cost and decreased quality of care, as well as a complete lack of support in the published literature, many experts and the ASA Guidelines on Chronic Pain do not support such a stance.

Such belief systems (e.g., 80% efficacy requirement) must be supported either by randomized controlled studies in peer-reviewed journals or by the use of a valid, large-scale outcome registry prior to their acceptance in an LCD that could have widespread impact on the health of patients.

However, despite the smaller differences, the various societies are unanimous in their rejection of the validity of a decision of non-coverage for facet therapy.

Outcomes Management

Another area of agreement among the various pain medicine professional societies is that there is a need for better population statistics and outcome data regarding the use of these procedures and others in patients with pain. Several organizations are working on outcomes registries that will help us get a much better picture of how these procedures are used, the results of their use and the patterns that will help us to get a better understanding of how to improve our outcomes. Primary among these efforts is the newly formed Anesthesia Quality Institute (AQI), a separate organization founded by the ASA.

The AQI is focused on quality improvement in anesthesiology and will establish a national clinical data registry for anesthesia and pain medicine.

The ASA leadership is pleased to learn that the Board of the AQI has committed to the creation of a comprehensive pain medicine outcomes registry as the very first segment of this larger clinical data collection. This commitment and the massive financial support provided by the ASA to this effort will result in the fastidious collection of outcomes data in pain medicine to better answer many of the outstanding questions of technique, efficacy, patient selection, etc. The ASA and AQI believe that as that registry becomes validated and completed, now estimated to be in place before the end of 2010, the physicians, patients and other stakeholders will have a powerful tool to explicate the answers to these questions and alleviate the burden created by the dearth of published evidence.

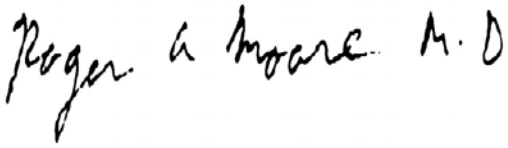
Conclusion

Once the several societies had met and extensively exchanged views on the appropriate performance of facet therapy, representatives of the ASA (Drs. Dunbar, Cohen and Merrill) met with Dr. Hecker, Medical Director for Noridian, at her request. At that meeting, a draft Local Carrier Decision (LCD) was presented to Dr. Hecker and a fair exchange of ideas ensued. As a result of that meeting, the attached LCD document was created and we recommend it to Noridian as an appropriate model to manage policy regarding facet treatments.

The ASA joins all the other professional pain medicine societies in strongly denying the scientific validity of a decision by any payer to wholly prohibit payment for the performance of facet therapies. While not in complete agreement on every detail, the pain medicine professional societies are united in their assessment that continued coverage for facet procedures is firmly based on the evidence. The ASA supports this conclusion and agrees that an LCD should be developed that maintains appropriate access to these valuable therapies.

Please do not hesitate to call upon the ASA for aid in development of an LCD that would support the coverage of facet therapies for your clients.

Sincerely,



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