Comments on a proposal to limit Medicare coverage of nerve decompression surgery

I have seen the text of a LCD document titled, "SURGICAL DECOMPRESSION FOR PERIPHERAL NEUROPATHY", LCD ID Number DL24716 and would like to contribute some comments based upon an extensive literature review. The bibliography used in the LCD document is not available to me.

The recommendation that coverage be denied for surgical decompression of diabetic and other forms of polyneuropathy seems based upon a narrowly selected review of available information, some of which is brought into question by recently published and presented science. I want to address some points mentioned in "Indications and Limitations of Coverage and/or Medical Necessity". To wit:

1. "**Double Crush" or "double pathology".** This descriptor has been used in some of the published studies on surgical nerve decompression for diabetic polyneuropathy to illustrate the concept that the metabolic damage of diabetes can have contributory effects in clinical nerve entrapments. Step number 1 is diabetes, step 2 is the resultant enlargement of nerve. Entrapment in anatomically restricted fibro-osseous tunnels results. This can be reproduced in the laboratory[1, 2] and can be demonstrated in humans by ultrasound and MRI.[3-5] This pathology is relieved by therapeutic surgical decompression of the nerve, gently opening the restriction and allowing recovery of nerve function.

   Recovery of sensation and relief of pain are the clinical outcomes reported in at least 17 studies, [6-15] summarized by Professor Dellon, originator of the therapy, at the 2006 Am. Diabetes Association Scientific Sessions[16] There are no scientific publications that purport to show absence of beneficial effect with this surgery, nor permanent harm induced. An analogous entrapment situation is present in leprosy neuritis, though with an infectious and immunological cause, for which an experience of > 50 years and a literature of several hundred reports exists which establish a therapeutic place for surgical nerve decompression in Hansen's Diesease.

   The relevance of the 1988 Dyck et al report of a protective effect of diabetes to axonal degeneration in rats with acute nerve crush to the prolonged chronic nerve enlargement and entrapment in clinical diabetic peripheral neuropathy is unknown. Few academics

2. **The American Academy of Neurology Practice Advisory[17].** The evidence of effectiveness and safety of the decompression surgical procedures in diabetic neuropathy is provided by anecdotal report, retrospective studies, prospective studies, comparative controlled studies and expert opinion. There are no prospective randomized, controlled clinical trials with masked outcome assessment. This current level of evidence requires labeling the surgery as "**unproven**". While it cannot at this time be labeled <u>possibly, probably</u>, or <u>established</u> as "**effective**", neither can it be designated "**ineffective"** or "**harmful".** The point is that there is not yet enough scientific evidence to form a valid conclusion. Lacking the science to determine this, Medicare has little basis for making an administrative determination that this surgery is "unnecessary".

   It may be of interest that the lead author of the AAN Advisory, Professor Chaudry of Johns Hopkins is involved in the planning stages of a randomized, prospective controlled trial designed to settle the academic uncertainty about benefits of surgical decompression for diabetic neuropathy. This can hardly be taken as a condemnation of the procedure, given the current state of the science.

3. **"Standard Testing"** Clinicians struggle with the diagnosis of nerve entrapment. The standard NCV (nerve conduction velocity) and EMG studies are plagued with false negatives in clearly symptomatic patients. Perkins and Bril [18] were unable to establish any valid electrodiagnostic discriminators in diabetes between diffuse neuropathy and clinical carpal tunnel syndrome and recommended that therapeutic decisions be made *independent of electrodiagnostic criteria.* So-called standard carpal tunnel syndrome may be a precedent or presenting symptom of diabetes[19]. Medicare does not require confirmatory electrodiagnostic testing before carpal tunnel surgery for reimbursement and there would be great added costs were it to do so. It is a significant problem

that there exists no objective, quantitative measure of pain or sensation, the major disturbances and patient concerns in diabetic foot neuropathy. All measures depend at least in part on patient report. This has complicated our ability to scientifically evaluate the value of therapies.

4. **Medicine is struggling to understand and treat diabetic neuropathy.** The reigning dogma explaining diabetic foot neuropathy is "length dependent axonopathy", often characterized as a "dying back" of the nerves in the legs due to metabolic damage. This theory implies that the process will be symmetric in the R and L feet. It should also be global in each foot, i.e. top, bottom, and sides should be equally affected. The AAN practice advisory specifically presumes this to be fact. Yet there is published evidence[20] and a sense among perceptive clinicians doing this work that it is not so. A recent study being prepared for publication suggests this is seldom the case. Rader and Barry report that the anatomic site of involvement and symmetric effect is quite variable, and is in fact rarely symmetric and global. This demonstration of an anatomic component in diabetic polyneuropathy certainly implies that Professor Dellon may be correct, nerve entrapment is likely a part of diabetic peripheral neuropathy, and there is good theoretical reason to expect nerve decompression to be effective therapy.

5. **Medicare approves and reimburses nerve decompression for diabetes**. Academic medicine recognizes that individual nerve entrapments occur in diabetes and that the appropriate treatment for it may be surgical decompression. There has been no squeamishness to recommend surgical treatment for the single nerve entrapments. None characterize it as unnecessarily risky in diabetes patients. Medicare reimburses carpal tunnel release, tarsal tunnel release, and other individual nerve neurolysis procedures without question, whether the patient be diabetic or not. It seems inconsistent to reimburse for a single entrapment, but not multiple events. The diagnosis in the diabetes patients could just as well be listed as entrapments of peroneal nerve, posterior tibial nerve, medial calcaneal nerve, medial and lateral plantar nerves and/or tarsal tunnel syndrome with secondary diagnosis diabetes mellitus. In that case I sincerely doubt there would be the any dispute about reimbursing surgical therapy. The concept which non-surgical academics cannot seem to grasp is that there is a generalized size change in diabetic peripheral nerve which makes them susceptible to entrapment *in combination* as well as singly.

6. **Indications.** Accepted indications[11] for surgical treatment of diabetic neuropathy in the feet are- an established diagnosis of diabetes, elimination of other possible neuropathy etiology, and a positive Tinel's sign over the areas of anatomic compromise. Advanced cases which have progressed past the point of ongoing damage and nerve recovery have a negative Tinel's sign and can expect a lesser chance (50% vs 80%+) of pain relief and sensory improvement .

7. **Outcomes.** In addition to the listed primary and secondary outcomes, a >90% reduction in recurrence of foot ulceration has been calculated from International Neuropathy Decompression Registry records[21]. There is an anecdotal report[22] that early use of nerve decompression may reverse the acute Charcot Foot process. Both outcomes would change the natural history of diabetic foot neuropathy[23] and could completely avoid in most patients the present costly progression of devastating foot problems, with ulcer leading to infection and ultimately amputation. No other therapy under development shows evidence it can permanently relieve neuropathic pain or restore protective sensation which prevents the grim cascade of diabetic foot complications.

8. **Medical Necessity and Treatment Recommendations**. Many current medical practices reimbursed by Medicare have never been subjected to randomized prospective trials against placebo controls (e.g. total joint replacement, cardiac angioplasty, etc). "Medically necessary" does not correlate to "possibly, probably, or established" effective treatments. Nor does "unproven" therapy equate to an "unnecessary" treatment. "Unnecessary" **does** equate to "ineffective" and "harmful" therapy. The recent CMS decision to withhold reimbursement for Anodyne therapy is an example of an appropriate administrative decision, based upon two separate scientific reports finding that monochromatic laser light therapy was not more effective than

placebo for pain relief or sensory return. There is no similar evidence that questions the efficacy of surgical nerve decompression for properly selected cases of diabetic neuropathy.

It is my hope that the New York hearing or evaluation will not prematurely abort a most promising therapy for the devastating foot complications of diabetes**.** Restricting access of Medicare patients to a therapy which can be life saving and life restoring before science has been allowed to complete its evolutionary course would be a great shame. Let this not be another breakthrough idea such as the bacterial etiology of peptic ulcer disease, which takes 20 years to progress from a breakthrough idea, initially ridiculed, to Nobel Prize for medicine. For the sake of our millions of diabetes patients with neuropathy, I urge patience and support for gathering of better information.

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Diabetic with neuropathy

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