October 24, 2017

Christine Ferrari, MD
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via Email: ferraric@aetna.com

Re: Headaches: Invasive Procedures, Number 0707

Dear Dr. Ferrari:

The Spine Intervention Society, a multi-specialty association of over 2,700 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of spine pain, would like to take this opportunity to comment on your coverage policy for invasive procedures for headaches.

The Society's membership includes many of the clinicians and academicians whose published literature provides the seminal references upon which the practice of evidence-informed interventional spine care is based. Our organization has a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved so that patients do not have to suffer or undergo more invasive and often unnecessary surgical procedures.

We note that Aetna's medical policy for headache and occipital neuralgia treatments specifically excludes third occipital nerve (C2-3) denervation or radiofrequency neurotomy (RF), suggesting that there is insufficient evidence to support its use. We are concerned that this is not consistent with the evidence in the literature and offer an explanation for our recommendation for coverage. For patients with suspected pain arising from the C2-3 zygapophysial joint, who have achieved greater than 80% relief of index pain with dual diagnostic blocks using appropriate techniques, third occipital nerve RF neurotomy is a proven, effective procedure.

In patients with chronic neck pain, the representative prevalence of cervical zygapophysial joint pain is in the order of 60% in patients.[1-5] This makes it the single most common basis for chronic neck pain, and the only condition that can be diagnosed using validated diagnostic tests. No other causes of neck pain have diagnostic tests that have been validated, and there has been no other cause in which the prevalence has

been determined. In patients with positive responses to controlled, medial branch blocks, the segments most commonly positive are C2-3 and C5-6 followed by C6-7.[5]

In 1994, a substantive study using controlled diagnostic blocks of the third occipital nerve, which is the innervation to the C2-3 zygapophysial joint[6], reported their yield in patients with headache after whiplash. [7] It reported a prevalence of 54% of headache stemming from the C2-3 zygapophysial joint.

It should be apparent that the C2-3 zygapophysial joint is a substantial pain generator not only in those with neck pain but in those with cervicogenic headache as well.[8] If non-invasive conservative care fails to provide adequate pain relief for those with pain originating from this articulation, then C2-3 zygapophysial joint denervation via third occipital nerve thermal RF neurotomy should remain a viable option for this substantial subset of patients rather than relegating these patients to continued suffering or reliance on analgesics.

It appears that Aetna's primary justification for classifying C2-3 zygapophysial joint denervation as a not covered procedure, as opposed to the cervical zygapophysial joints at levels below C2-3, is the absence of a randomized controlled trial addressing this specific joint. There has been a seminal RCT on cervical medial branch neurotomy that demonstrates that the positive outcome of the procedure is clearly not due to placebo effects.[9] This study did not access the C2-3 level due to documented technical limitations of RF neurotomy of this level (at the time of the study) attributable to anatomic variation of its nerve supply (third occipital nerve).[10] More recently, following the Lord RCT, the technical limitations of the RF technique have been addressed, which compensates for the unique anatomy of the third occipital nerve.[11]

Prospective observational evidence outside of RCTs can demonstrate the effectiveness of a procedure. In fact, when the outcomes of well-performed prospective trials demonstrate dramatic and sustainable results that are reproducible across studies, one could argue that the need to demonstrate that the effects of the procedure are not due to placebo effects alone are seriously minimized. This is more so the case when the procedure itself is in the same region of the spine for essentially the same anatomical condition (zygapophysial joint pain) and when the index procedure has already been shown to be effective in an RCT, for which the results cannot be attributed to a placebo effect.[9] This is indeed the case for C2-3 zygapophysial joint denervation, as compared to other cervical zygapophysial joints.[11]

Since the third occipital nerve RF technique has been appropriately modified following the seminal Lord RCT, three studies evaluating the effectiveness of third occipital nerve neurotomy have been published.[11-13] In a prospective trial, Govind specifically investigated the efficacy of radiofrequency neurotomy of the third occipital nerve for the treatment of headache via a modified technique.[11] Modifications to the technique used included: using a large gauge electrode; holding the electrode firmly in place throughout

the period of coagulation; and placing consecutive, parallel lesions no further than one electrode-width apart. As a result of these modifications, previous results of third occipital neurotomy were reversed. Instead of four out of 10 patients obtaining relief,[10] 86% of 49 patients obtained complete relief of pain. At the time of publication, the median duration of relief was 297 days, with eight patients experiencing ongoing, complete relief. Of the 14 patients who underwent repeat neurotomy when their pain recurred, 12 (86%) regained complete relief. In regards to the safety profile of third occipital nerve neurotomy, it should also be noted that there were no major complications, and side effects (dysesthesia, ataxia, local itchiness) were self-limited and resolved within 7-10 days, apart from one patient having a side effect for 4 weeks.

Another study was undertaken to explicitly test if the outcomes reported in the controlled trial could be replicated in conventional practice; it showed that they were.[12] Of 35 patients treated, 21 (60%) obtained complete relief of pain for at least 12 weeks in the first instance and for a median duration of 44 weeks. In this study, treatment was provided at the C2-3 level in 50% of the patients.

In the third study, two clinicians evaluated their outcomes after being trained in proven technically effective lesioning techniques.[13] The outcomes of all their consecutive patients over five years in their respective practices were audited. Treatment was provided at all levels from C2-3 to C6-7, and C2-3 was the most common level treated. The criteria for a successful outcome were complete relief of pain for at least six months, accompanied by restoration of activities of daily living, return to work (if applicable), and no further need for any other health care for their index pain. In the two practices, 74% and 61% of patients achieved a successful outcome. Relief lasted a median duration of 17–20 months from the first radiofrequency neurotomy, and 15 months after repeat treatments. Allowing for repeat treatment, patients maintained relief for a median duration of 20-26 months, with some 60% still having relief at final follow-up.

These studies clearly demonstrate that 60-86% of patients with C2-3 facet pain can be effectively rendered pain free for a duration of relief from 10-17 months. No other non-surgical treatment in the cervical spine can rival this degree and duration of relief. There are minimal to no high-quality rigorous trials of non-invasive conservative care (*i.e.* physical therapy, chiropractic, medications) for sub-occipital neck pain or cervicogenic headache, to aid in drawing comparisons to third occipital nerve neurotomy regarding efficacy or cost-effectiveness. When considering potential surgical treatments, cervical fusion is the only valid consideration. However, fusion is rarely indicated; primarily when there is C2-3 segmental instability or spondylolisthesis. Even in properly selected patients, surgery of the upper cervical spine has a relatively high morbidity and mortality, and surgery may be contraindicated in some patients. Preservation of access to a proven, effective treatment is particularly critical when there are few valid, proven, and equally safe alternative options.

An RCT establishing that the results of third occipital nerve RF neurotomy are not due to placebo effects as an absolute condition of coverage is not necessary in light of the magnitude of effects for this intervention when appropriately performed on the correct patients,[14-16] but one important consideration has been often overlooked. It would be impossible to perform a true blinded RCT on C2-3 facet RF. Patients who receive an effective third occipital nerve neurotomy develop time-limited neuropathic symptoms followed by cutaneous numbness in the distribution of the nerve. The active arm would clearly be aware of such symptoms and know they received the treatment and those that receive the sham would not have such symptoms. Additionally, those that receive diagnostic third occipital nerve blocks also develop temporary numbness in the same distribution and learn that such is associated with an active block and this would be an expectation following a technically well performed active C2-3 facet neurotomy.

It is our recommendation, consistent with local coverage determinations proposed by the Multisociety Pain Workgroup and adopted by several Medicare Contractors, that for patients with suspected pain arising from the C2-3 zygapophysial joint, who have achieved greater than 80% relief of index pain with dual diagnostic blocks using previously described techniques, third occipital nerve RF neurotomy should be a covered procedure.

We hope that this information, as well as any dialogue and collaboration between Aetna and the Spine Intervention Society, will lead to the establishment of a reasonable coverage policy that will eliminate inappropriate utilization while preserving access in appropriately selected patients. We offer our ongoing input and expertise in this matter. If we may answer any questions or provide any assistance, please feel free to contact Belinda Duszynski, Senior Director of Policy and Practice at bduszynski@spinalinjection.org.

Sincerely,

Timothy Maus, MD
President
Spine Intervention Society

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