October 7, 2016

Craig Haug, MD
JK MAC Medical Director NHIC, Corp.

Hewlett Packard Enterprise
75 William Terry Dr., Hingham, MA 02043

Dear Dr. Haug:

RE: Request for coverage and reimbursement for mechano-chemical venous ablation “Clarivein”

Dear Colleague:

The Society of Interventional Radiology (SIR) is writing this letter to request coverage for mechano-chemical venous ablation.

We respectfully ask you to reconsider your designation of mechano-chemical venous ablation (MOCA) as investigational. Marketed in the US as the Clarivein system, the efficacy, safety and resultant improvement in quality-of-life that results from the use of this FDA-approved device is supported by a number of publications in peer-reviewed journals.

Procedure and mechanism of action:

Endovenous mechanochemical ablation (MOCA) is a procedure that is used to close refluxing saphenous veins and their primary tributaries utilizing a mechanism of direct intimal injury within the lumen of the vein which purposefully abrades the intima and causes venospasm to allow for better efficacy of the sclerosant which is simultaneously injected. Since this ablation method does not use thermal energy, the potential for saphenous or sural nerve damage is minimized.

Following ultrasound imaging and marking of the patient’s anatomy on the skin and a sterile prep and draping of the patient’s extremity, a disposable catheter connected to a disposable motor drive is inserted into the target vein and advanced to just below the deep vein junction. As the catheter is slowly pulled back, a wire rotates at 3500 rpm within the lumen of the vein, abrading the intima. At the same time, a liquid sclerosant (sodium tetradecyl sulfate) is infused near the rotating wire. It has been demonstrated
that the combination of the mechanical and chemical effect results in vein closure better (1) than either method alone. The closure occurs with less pain (2) and reduced risk of saphenous or sural nerve injury (since there is no heat to injure the nerves) without the need for the tumescent anesthesia used with thermal endovenous ablation techniques (radiofrequency ablation [RFA] and endovenous laser treatment [EVLT]).

In terms of evidence supporting mechanicochemical ablation (MOCA), I would submit that the published data has demonstrated a high rate of success, a low complication rate, and the procedure has some advantages over some of the alternate available treatments. ClariVein® achieved FDA clearance through the 510(k) process in March 2008.

**Supporting Data:**

Supporting publications include a randomized controlled trial for treatment of the refluxing great saphenous vein (GSV), comparing MOCA with radiofrequency ablation procedure that has been approved by the FDA since 2000 (2). Several additional publications also support the safety and high rate of success of MOCA, similar to that following thermal ablation. (3-12). I present below a summary of some of the highlights of this literature.

a. *Bootun et al.*, (2) conducted a randomized, controlled trial to assess intra-operative pain between MOCA and RFA in 117 patients/119 limbs (MOCA: 59; RFA: 60). Pain scores were measured using a validated 100 mm visual analogue scale (VAS) with mean maximum results being 19.3 mm for MOCA and 34.5 mm for RFA. The study demonstrated less intra-procedural pain for MOCA with equivalent improvement in clinical and patient-reported quality of life measures at one month with similar occlusion rates as documented by Duplex US. MOCA showed a faster return-to-work and normal activities. MOCA was associated with no adverse events, while RFA patients had a 3.4 percent incidence of thrombophlebitis and 1.7 percent incidence of non-occlusive popliteal vein deep vein thrombosis.

b. A number of comparative trials and prospective cohort studies have drawn similar conclusions. Among these studies was one by *Ozen* (3) which looked at the 2-year results for MOCA treatment of the refluxing great saphenous vein. At that time interval, the saphenous occlusion rate was 95 percent, which was seen along with a significant decrease in a physician derived score of the severity of venous disease in the treated limb (Venous clinical severity score or VCSS).

c. *Boeersma* (5) demonstrated the safety and efficacy of MOCA in the small saphenous vein as well, with a 94 percent 1-year occlusion of the treated vein with no major complications and decrease in the VCSS and patient reported pain score.
d. *Vun et al.*, (12) assessed procedural pain for MOCA, RFA and endovenous laser ablation (EVLA) in 127 patients/147 veins (MOCA: 57; RFA: 50; EVLA: 40). Pain scores were collected by a nurse, blinded to the procedure, using VAS. Median pain scores were as follows: MOCA-1, RFA-5, EVLA-6. Technical success as evidenced by occlusion was similar for all three modalities with no major complications reported.

e. *Van Eekeren et al.*, (10) studied postoperative pain and early quality of life after RFA and MOCA in 68 patients (34 to each group). Occlusion rates were over 90 percent in each group. Pain was assessed with a 100 mm VAS and found mean procedural pain to be 22 mm for MOCA and 27 mm for RFA. Post-operative pain was measured at days 3 and 14 with MOCA mean pain to be 6.2 mm and 4.8 mm, while RFA mean pain was 20.5 mm and 18.6 mm. This demonstrated a 74 percent comparative reduction in post-operative pain at day 14. RFA patients were shown to use post-operative analgesics for 2.8 days on average compared to 0.5 days for MOCA patients. The median Venous Clinical Severity Score (VCSS) at week six showed a decrease from 3.0 to 1.0 for MOCA, while the RFA group decreased from 4.0 to 3.0. Quality of life outcomes were measured using the Aberdeen Varicose Vein Questionnaire (AVVQ) at 6 weeks and showed a change for the MOCA group from 7.1 to 5.0, and 9.5 to 4.5 in the RFA group. The authors stated that this was not clinically significant. MOCA and RFA patients returned to normal activities in one day, but the RFA group tended to take an extra day before returning to work. There were no major complications in either group.

Finally, I would like to note that the Society of Interventional Radiology, in partnership with the Society of Vascular Surgery and the American College of Phlebology, presented supportive testimony at the October 2015 CPT Panel meeting for this procedure. The AMA CPT panel decided that mechano-chemical procedures (MOCA) met the criteria for a CPT Category I code, and two new codes describing MOCA will go into effect in 2017.

Thanks for the courtesy of your review of this request, and I am available to go into further detail at your convenience.

Respectfully,

Charles E. Ray Jr., MD, PhD, FSIR

2016-2017 SIR President

Selected Bibliography


