

## Commissioning Statement

<b>Treatment</b>	<b>Vibro-Pulse cycloidal vibration (CV) therapy</b>
<b>For the treatment of</b>	<b>Cellulitis, venous leg ulcers and lower limb oedema.</b>
<b>Commissioning position</b>	<p>.....CCG does not routinely commission the use of Vibro-Pulse cycloidal vibration therapy.</p> <p><b>Review patients currently receiving prescriptions for these products. Discontinue prescribing on FP10 and do not start new patients.</b></p>
<b>Date effective from</b>	.....November 2019
<b>Policy to be reviewed by</b>	.....November 2022
<b>Background information</b>	<p>Vibro-Pulse® uses cycloidal vibration (CV) therapy and is promoted as a therapy for cellulitis, venous leg ulcers and lower limb oedema. The company claim that stimulating the microcirculation in the infected area can enhance potential delivery of antibiotics to the tissues and reduce the associated oedema.</p> <p>CV therapy is a form of 3-dimensional oscillating vibration with a small-amplitude and low frequency waveform. When applied to the skin, it is claimed to increase microcirculation and fluid flow in the soft tissues. It is used in a variety of devices on the market and is claimed as a therapy for a range of conditions including arthritis, tennis elbow, sciatica, varicose veins, night cramps, swollen ankles, spinal disorders, leg ulcers, frozen shoulder and insomnia.</p> <p>The recommended regimen is one 30-minute treatment three times a day, a disposable cover being required each time the device is used.</p> <p>The device itself is not prescribable on FP10 and is provided on loan from the company at no cost.</p> <p>The company suggest an initial treatment phase of 14 days for leg ulcers, oedema or other wounds. After this time, if no improvement is seen, treatment with Vibro-Pulse® should be stopped. If improvement has occurred, Vibro-Pulse® can be continued until the ulcer is healed or until no further improvement is seen. The cost of Vibro-Pulse® is currently £420 per 28 days.</p> <p>The disposable covers are included in the drug tariff at a cost of £15 for a pack of three (one days treatment)</p>
<b>Summary of evidence/rationale</b>	A Cochrane review of treatments for cellulitis concluded that there was insufficient evidence on CV therapy to form a

	<p>conclusion about the efficacy of such treatment.</p> <p>There are currently insufficient data on the chronic use of Vibro-Pulse® for venous leg ulcers or other wounds to recommend its use.</p> <p>Few published papers are available for CV therapy.</p> <p>One clinical trial has been published of Vibro-Pulse® in the management of cellulitis.</p> <p>One prospective, company-sponsored, non-blinded, randomised controlled trial has been published using VibroPulse® for lower limb cellulitis<sup>2</sup>. Thirty-six patients with leg cellulitis were randomised to receive either standard therapy (intravenous or oral antibiotics plus bed rest - control group) or standard therapy plus CV therapy three times daily (CV therapy group). The trial was conducted in a hospital setting. Patients were followed up for 7 days. The primary outcome measure was the recovery time, defined as 100% reduction in erythema/ cellulitis. Other outcomes included pain scores, reduction in area of erythema/ cellulitis and amount of leg oedema.</p> <p>No clinical trials have been identified of CV therapy for other indications.</p> <p>Data are only available for a small number of patients and from non-blinded or retrospective studies.</p> <p>A Cochrane review of treatments for cellulitis concluded that there was insufficient evidence on CV therapy to form a conclusion about the efficacy of such treatment (1).</p> <p>Available data are inadequate to assess any impact of Vibro-Pulse® on healing rates or calculate cost-benefits.</p> <p><u>References:</u></p> <p>1. Kilburn SA, Featherstone P, Higgins B, Brindle R. Interventions for cellulitis and erysipelas. Cochrane Database of Systematic Reviews 2010, Issue 6. Art. No.: CD004299. DOI: 10.1002/14651858.CD004299.pub2.</p>
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