Comments submitted to NICE by the Neuromodulation Society UK and Ireland

Re: SCS Assessment Report for Consultation

General Comments on the document contents

SCS in CRPS

The Physiotherapy Program followed in the Kemler paper is described as a graded exercise program aimed at improving strength mobility and function. During the exercises pain was considered acceptable. The physiotherapy program lasted for 6 month for all patients. This is clearly different from UK physiotherapy practice where the duration of therapy seldom exceeds 3 months and the therapy is always impeded by pain, which is considered unacceptable. This would tend to favour the results of the control group if the study is interpreted in a UK context.

The document presents the results of the 5-year follow up study by Kemler et al (recently published in Full Feb 2008) without any discussion of factors that may have affected these results (Numbers lost to follow up and cross over) and the influence that has on the results

In the Kemler study population (control group) there was a trend to spontaneous pain improvement at the 5 year follow up, this was not mirrored in the largest prospective study of referred CRPS patients which did not confirm a correlation between duration of CRPS and differing sets of symptoms and signs (Veldman PH, Reynen HM, Arntz IE, et al. Signs and symptoms of reflex sympathetic dystrophy: prospective study of 829 patients. 1993; 342:1012–1016.Lancet) A more recent study by M Vaneker at (Vaneker M,. Wilder-Smith O, Schrombges P, et al. Impairments as measured by ISS do not greatly change between one and eight years after CRPS 1 diagnosis European Journal of Pain 10 (2006) 639–644) followed up 45 CRPS sufferers for 8 years. The study concluded that considerable impairments were still present over 8 years after the initial CRPS diagnosis and that the impairments including VAS scores did not change much between one and eight years post-diagnosis. This may point to the fact that the Kemler study population may well be a special subset of CRPS patients. This again would bias the results in favour of the control group

SCS in Refractory Angina:

The disease considered as a target for SCS is Refractory Angina rather than ordinary angina pectoris unfortunately the document does not make this distinction clearly in the description of the health problem section. (Page 7 paragraph 3) although RA is mentioned later in the clinical effectiveness section (page 42) and in the threshold analysis (page 82 paragraph 1).

In a clinical context, in the UK, SCS is used exclusively for patients suffering from refractory angina. This is a subset of the AP population where despite maximal medical and surgical intervention the patient continues to suffer from severe disabling angina

attacks. Therefore by definition a further CABG or PCI in this group of patients would be considered futile or too dangerous. In all the trials considered candidates were thought not to benefit from a CABG. The threshold Analysis for angina however compares SCS to CABG and PCI, which is inappropriate in terms of the UK practice as these therapies are not available to the RA group.
Finally it is our experience as UK clinicians that the longevity of entry level IPG far outlasts 4 years in RA patients, as they tend to use the SCS to terminate attacks and occasionally as a prophylactic measure prior to effort. The device longevity has a significant bearing on the Cost/QALY of the intervention.

SCS in CLI:
All the studies mentioned in the report have no specific selection criteria apart from Fontaine Staging. The Amann study [100] developed such selection criteria to identify a subset of CLI patients who were indeed shown to benefit from SCS by a significant reduction in the amputation rate in SCS group vs. The CMM group. This study was not included in the report as it is not a randomised study by virtue of its design. This study is mentioned by the authors (page 38 last paragraph) in the context of developing selection criteria. A more detailed presentation of this paper would have been desirable as part of the discussion of SCS in CLI.

Specific comments:
Page 4,5 Cost of SCS device in CRPS
It is our member's clinical experience that more often than not the device longevity for simple entry level IPGs (Itrel II or III) is more than 4 years in CRPS of upper limb because of the CSF distance separating the electrode from the Spinal cord which leads to low voltage requirements and therefore longer battery life. The same results can be obtained in lower limb CRPS by employing a retrograde lead implant technique. Indeed in the Kemler study 9/22 patients only had required battery replacement at 4 years and 5 patients exceeded the 5-year mark
Complex system costing 15000 are unlikely to be used routinely in cases of CRPS. As they are technically not required to provide coverage of a single limb.

Page 7 in Definition of the disease paragraph 4 there is no clear description of refractory angina is given

Page 11
Under guidelines it is important to take into consideration that recommendations by the British Pain Society (BPS) were drawn up and published prior to the full publication of the PROCESS study results. As well as the Kemler study 5-year follow-up data

Page 12 last paragraph under description of the technology:
SCS has several advantages. It is completely reversible low invasiveness compared to traditional surgery and offers the patient the potential to trial the therapy, which is not possible with traditional surgery or most conventional therapies. While test or trial stimulation as it is known clinically may not determine long term outcome it important

from a patient point of view as it gives them an opportunity to ascertain the nature and the distribution of the paraesthesias they are to experience in the case of a long term implant

Page 85The study used to predict the utilities and QALYs in RA (Griffin at al 2007) is a study of the general angina population as opposed to the Refractory Angina population. The RA population are by definition higher consumers of health services. This may influence the cost estimation in the CMM group

Page 76 FBSS assuming that CMM patients experience no complications based on Swedish data for surgery (surgery is not the main comparator in UK and types of procedure varies. Also (page 78 the cost of CMM is estimated to fall by 17.8% after the first year compared to the cost of year 1. While the cost of CMM will fall after the first year it is unsafe to extrapolate Canadian data to the UK system as FBSS patients are high health care consumers and ease of access to medical services will determine This may well be different between the UK and Canada)

Page 83 cost of trial estimated from Canadian data which is over evaluating the costs as in our experience costs of GP consultation, Pain consultation, psychology consultation + physiotherapy

On behalf of NSUKI board

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Neuromodulation Society UK and Ireland
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