National Institute for Health and Clinical Excellence

IP1067 – Peripheral nerve-field stimulation for chronic low back pain

Consultation Comments table

IPAC date: 17 January 2013

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS Professional	**1.1**	"Agree with guidance as limited evidence the guidance is reasonable I disagree with the statement regarding limited evidence of safety as 2 case series of 100 and 111 patients are possibly large enough to show safety comparable to if not better than SCS"	Thank you for your comment. The consultee is referring to 2 papers (Sator-Katzenschlaer 2010; Verrills 2011) included in the systematic review. The Committee agreed to add the studies to the Guidance. The Committee considered the comment but decided not to change the guidance.

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2	Consultee 2 Manufacturer	**1.1**	Section 1.1. states that “current evidence…is very limited, in both quantity and quality. Evidence on safety is also limited” We agree that the literature base on PNFS is currently limited, however the available data to date do show treatment efficacy over the short term and there is no reason to think that initial early response will not be maintained in the same way as it is in SCS. This is being examined in larger ongoing trials. The current wording does not reflect this, and we suggest that the wording could be aligned with other published or provisional IPG recommendations with Special Arrangements. For example, the current Occipital Nerve Stimulation (ONS) IPG draft consultation states “evidence shows some efficacy in the short term, but limited in long term outcomes”. Further reasons why this should be amended include: - The percutaneous lead implant technique for PNFS parallels that of the well-accepted Spinal Cord Stimulation (SCS) technique. SCS has already been demonstrated to be highly clinically and cost-effective (NICE TAG 159); as PNFS is a more conservative variation of the same technique and it could reasonably be expected to show similar long term clinical efficacy and safety outcomes. - As a PNFS trial is conducted prior to the permanent implantation, patients can be effectively screened before receiving the therapy, ensuring that patients who do receive the permanent implant will respond positively. As therapy outcomes can be ascertained in each patient prior to implant, clinical effectiveness, at least in the short term, should not be in dispute. -	Thank you for your comment. The IP Programme does not consider Peripheral Nerve Field Stimulation (PNFS) to be a minor variation of Spinal Cord Stimulation (SCS). This decision was based on input from Specialist Advisers who advised that the procedure being considered for possible guidance was not a minor modification of an existing technique. The Committee considered the comment and section 1.1 of the Guidance was changed.

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3	Consultee 1 NHS Professional	**2.1**	It should be noted that this Â is an entirely reversible porcedure spinal fusion and disc replacement are not and can cause Â far Â more life threatening complications	Thank you for your comment. Section 2.2.3 of the Guidance states that the system can be removed. The Committee considered the comment and section 2.2.1 of the Guidance was changed.
4	Consultee 1 NHS Professional	**2.2**	Agree	Thank you for your comment.

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5	Consultee 2 Manufacturer	**2.3**	• This section references only two studies, both cases series. An RCT (n=30) was identified in the systematic review (reference #71) but not included in the IPG because it is in conference abstract form only and not published. This is reasonable however it is not consistent with the IPG consultation on ONS, where an RCT in abstract form has been included (reference #17). ○ In light of this, RCT (ref #71) should be included. • Further, the retrospective study with 3 month follow-up by Sator-Katzenclager, 2010 (ref. #76) was identified but the results were not included as it was categorized as 'mixed types of pain'. We would like to highlight that this trial included sub-set analyses of FBSS patients (n=37) and low back pain (n=29), with a reduction in pain reported in 92% of patients; and mean pain intensity reduced from 8.0 to 3.3 following implant in FBSS patients. ○ We would like to request that this information is provided within this section of the IPG.	Thank you for your comment. The consultee has cited a conference abstract Barolat (2011) [ref 71] referred to within the systematic review. The NICE IP Methods Guide states that efficacy data from non peer-reviewed studies are not normally presented to the Committee. A peer-reviewed published paper of the RCT (Silberstein 2012) was included in the addendum to the systematic review (evidence relates to Occipital nerve stimulation for intractable chronic migraine). Additional data from the Sator-Katzenclarger (2010) study was added to section 2.3 of the Guidance.

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6	Consultee 1 NHS Professional	**2.3**	"unfortrunately you seem to have missed the two largest case series in the literature in your assessment The 2 largest case series include 100 and 111 patients respectively Â Refs1. Sator-Katzenschlager, S., et al., Subcutaneous target stimulation (STS) in chronic noncancer pain: a nationwide retrospective study. Pain Pract, 2010. 10(4): p. 279-86. 1. Verrills, P., et al., Peripheral nerve field stimulation for chronic pain: 100 cases and review of the literature. Pain Med, 2011. 12(9): p. 1395-405."	Thank you for your comment. Regarding Sator-Katzenschlager (2010) please see response to comment 5. The Verrills (2011) paper cited by the consultee was added to section 2.3 of the Guidance.
7	Consultee 1 NHS Professional	**2.4**	the 2 large case series mentioned above, Â while not all back pain they do show a better safety record that SCS	Thank you for your comment. Where safety outcomes were not reported separately for the low back pain group, the results have not been reported in the Guidance.
8	Consultee 2 Manufacturer	**2.4**	o PNFS is a minor variation on an already existing well-accepted technique (SCS), therefore it would reasonably be expected to show similar safety outcomes. Nature of adverse events experienced are similar to what is seen with SCS i.e. lead migrations, pain at implant site, etc. No additional type of AE has been experienced other than what has been observed with SCS.	The IP Programme does not consider Peripheral Nerve Field Stimulation (PNFS) to be a minor variation of Spinal Cord Stimulation (SCS). This decision was based on input from Specialist Advisers who advised that the procedure being considered for possible guidance was not a minor modification of an existing technique. This procedure was considered to be sufficiently different from SCS and with potential for different safety and efficacy profiles.

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9	Consultee 1 NHS Professional	**2.5**	Agree	Thank you for your comment.
10	Consultee 2 Manufacturer	**2.5**	o There is an ongoing RCT (SubQStim study) enrolling 200 patients to address the limited safety and efficacy data: Interventional, Prospective, Multicenter, Randomized, Parallel-arm Study to Compare the Effectiveness of Peripheral Nerve Stimulation (PNS) Utilizing a Subcutaneous Lead Implant Technique (SQS) Plus Optimized Medical Management (OMM) Versus OMM Alone in Patients Suffering From Back Pain Due to Failed Back Surgery Syndrome (FBSS).	Thank you for your comment. The NICE IP Methods Guide states that efficacy data from non peer-reviewed studies are not normally presented to the Committee. Details of this ongoing trial have been added to the systematic review.