National Institute for Health and Clinical Excellence

877 – Percutaneous tibial nerve stimulation for faecal incontinence
Consultation Comments table
IPAC date: Thursday 10 March 2011

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Medical Device Industry	**1.1**	1.1 The PTNS treatment for faecal incontinence (FI) raises no major safety concerns. The adverse events are minor and transient, far fewer than those associated with Sacral Nerve Stimulation (SNS) or surgery. 1.3 In the prepared overview is described that the patient can administer the current themselves at home. We agree with the provisional recommendation that the procedure should be carried out in only in units specialising in the assessment and treatment of faecal incontinence, as one of a range of treatment options. We believe that administering treatment themselves at home therefore should not be advocated and request that this sentence be deleted.	Thank you for your comment. The overview will be changed.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
2	Consultee 2 NHS Professional	**1**	The Urgent PC device has CE certification for use in patients with FI, and is not an experimental treatment. We have been undertaking this treatment since January 2008 and have a series of about 175 patients. Data has been collected at baseline, end of initial treatment and at follow up treatments for all these patients as follows and is currently being collated: number of incontinent episodes per week, ability to defer defaecation, Wexner scores, quality of life scores, HADS, effect of treatment on UI (if appropriate). We also have some qualitative data on life before PTNS, life after PTNS and perceptions of treatment A national multicentre RCT on PTNS in FI is shortly to commence under the guidance of Mr C Knowles	Thank you for your comment. An early publication from this centre was included in table 2. A later publication has been referred to in comment 7 and will be added to appendix A of the overview.
3	Consultee 1 Medical Device Industry	**2.1**	The placement of PTNS within the algorithm of FI treatment can be used in patients refractory to conservative treatments and on those patients who are not candidates for more invasive surgery such as sacral nerve stimulation nor surgery.	Thank you for your comment. This is addressed in the first sentence of section 2.2.1.
4	Consultee 2 NHS Professional	**2.1**	There should be an indication of where PTNS falls in the treatment pathway. At our tertiary referral centre, patients with minor FI are managed as in 2.1.2. However, most patients now have PTNS as first line management. Our rationale for this is because this is a TREATMENT. Other first line measures are directed towards symptom control and there is ample research to demonstrate that effects of biofeedback etc wear off over time, probably because patients lapse in implementing them. PTNS provides a treatment which enables patients to avoid medication, exercises and dietary manipulation, and to live an ordinary life. Therefore it would appear to have benefits above those of conventional first line management.	Thank you for your comment. The Interventional Procedures programme at NICE assesses the safety and efficacy of new interventional procedures. The Committee makes recommendations on conditions for the safe use of a procedure including training standards, consent, audit and clinical governance. It does not have a remit to determine the placement of a procedure in the pathway of care for a disease or condition.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
5	Consultee 1 Medical Device Industry	**2.2**	Initial treatment consists of 12 outpatient sessions lasting 30 min each, typically once a week. On-going treatment will be performed and adjusted to the patient's personal need varying from once every two weeks to once a year. In the prepared overview in the Specialist Advisers' opinions it states that two Advisers considered the procedure to be novel and of uncertain safety and efficacy. It will be evident that if the safety was uncertain the treatment would not have received a CE mark for the indication of FI. In reference, the PTNS treatment for Overactive Bladder Symptoms is based on exactly the same procedure. PTNS for Overactive Bladder syndrome NICE IP guidance 362 states that there are no major safety concerns for the PTNS procedure.	Thank you for your comment. The guidance is not a comprehensive description of the procedure. The overview points out that this is adjusted depending on the patient's response to treatment. The opinion of the Specialist Advisers is summarised in the overview and will not be changed.
6	Consultee 2 NHS Professional	**2.2.2**	2.2.2 Treatment is effective with EITHER sensory or motor response. A full first treatment has 12 sessions which are immediately followed by two more sessions 2 weeks apart and one treatment 1 month after this. This weaning off is important - a few patients symptoms return during this time, so they receive 2 - 3 further sessions and then weaning off is tried again	Thank you for your comment. Section 2.2.2 of the guidance will be changed to state 'motor and/or sensory' response'. A statement about repeat treatments will be added to the guidance.
7	Consultee 1 Medical Device Industry	**2.3**	-The reference of Govaert B et al. in table 2 can be updated with the actual publication date: Colorect Dis 2010 12(12) : 1236-1241). -Reference 7 of Table 2 of Queralto should be taken out since the procedure in the study described is based on a transcutaneous neuromodulation technique, which is different from percutaneous and thus will result in different numbers of efficacy. -Please note a recent case report published online in Int J Colorectal Dis DOI 10.1007/s00384-010-118-z by Allahdin S, Oo N, Jones C. Intractable flatus incontinence treated by percutaneous tibial nerve	Thank you for your comment. The reference to the study by Govaert B et al will be updated in the overview. The study by Queralto will be removed from the overview. The case report by Allahdin et al (2011) will be included in Appendix A of the overview. Peters et al (2010) refers to results published as an abstract. Allison (2011) appears to have been published and/or indexed after our updated literature search. The study has been added to Appendix A.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
			stimulation. The patient showed an improvement of 60% in her symptoms and a 70% improvement in the effect of her symptoms on her quality of life. At 6-month follow-up she reported a continuous effect of the treatment This reference could be added to table 2. -Please note the presentation of a cross sectional review of effect of PTNS on FI: results from Â two recent OAB trials, presented by Peters K, Carrico D, Siegel S, Wooldridge L, MacDiarmid at ICS-IUGA 2010 (abstr. 528), Toronto, Can The abstract describes an improvement in symptom relief of FI after 12 PTNS treatments in 13/16 subjects (81%) -Just very recently an article was published in the Nursing Standard 2011; 25(24)-44-48 by M. Allison describing PTNS treatment for 114 patients with faecal incontinence in the Royal London Hospital Centre for Academic Surgery. Not all patients have finished the treatment yet, but of the 90 that have finished the course 77% have demonstrated an improvement in their condition, with a reduction in incontinence episodes by at least 50% as recorded in a bowel habit diary. This reference could be added to table 2.	
8	Consultee 2 NHS Professional	**2.3**	The other most significant benefit consistently described by patients (and the one they usually notice first)is an increased ability to defer defaecation (i.e reduced urgency)	Thank you for your comment. The efficacy in the guidance is only a summary of the results from the included studies. More detail is provided in the overview.
9	Consultee 1 Medical Device Industry	**2.4**	Yes, the PTNS treatment for faecal incontinence (FI) raises no major safety concerns. The adverse events are minor and transient.	Thank you for your comment.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
10	Consultee 2 NHS Professional	**2.4**	Throbbing pain at insertion site is usually because the needle is not advanced sufficiently (i.e related to technique) We have had no instances of gastrodynia, leg numbness, haematoma or inflammation. Rarely there is slight bleeding on withdrawal of the needle. One patient reported worsening of sciatica and discontinued treatment.	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.
11	Consultee 1 Medical Device Industry	**2.5**	In the overview describe issues for consideration by IPAC other trials in progress are listed: The RCT at North West London Hospitals NHS Trust comparing PTNS with sham (NCT005530933) is funded by Uroplasty. As far as known Uroplasty is not funding this trial.	Thank you for your comment. The overview will be changed. NICE has been advised by that the study is completed but that the results have not yet been accepted for publication.
12	Consultee 2 NHS Professional	**2.5**	It is important to note that this treatment is expected to be effective for about 6 months and it will wear off in time if maintenance or top up treatments are not given (similar to those described in the body of work on PTNS for UI, but FI treatment lasts longer). Two regular top up treatments are scheduled at 6 months after the initial treatment and twice a year thereafter indefinitely. Those whose treatment is successful can avoid a return of symptoms on this regime. Effectiveness is expected to gradually wear off if patients go for a long time without regular top ups. There is a misconception in some of the literature about failure of PTNS related to this issue - PTNS is an ongoing treatment, not just a one off initial course. Also cost benefit. The initial course of treatment is cheaper than any surgical option. Cost of maintenance treatment per year is cheaper than pad use.	Thank you for your comments. A section on repeat treatments will be added to section 2.2.2 of the guidance. Cost-effectiveness is not part of the remit of the IP Programme. No further changes will be made to the guidance.