Title:	Sacral nerve stimulation for urinary indications
Agency:	Medical Services Advisory Committee (MSAC) MDP 106 Commonwealth Department of Health and Ageing GPO Box 9849 Canberra ACT 2601 http://www.msac.gov.au
Reference:	MSAC Application 1115 Assessment report First printed January 2009 ISBN (print) 1-74186-790-8

# Aim:

To assess the safety, effectiveness and cost-effectiveness of sacral nerve stimulation (SNS) for the treatment of refractory detrusor overactivity, non-obstructive urinary retention and painful bladder syndrome through a systematic review of the literature.

# **Results and Conclusions:**

Safety:

Comparative safety data were not available for this procedure. The SNS procedure was not reported to be associated with any mortality, and the majority of adverse events experienced were of a relatively minor nature. The most common adverse events were a requirement for lead revision or replacement (241/1444 patients; 16.69%) and unspecified pain (205/901 patients; 22.75%). The safety profile of the procedure appears to be improving with modifications to the device (tined leads) and surgical technique (buttock placement of generator).

# Effectiveness:

#### Detrusor overactivity

Two randomised controlled trials indicated that SNS was more effective than standard medical management in significantly improving a number of key voiding variables, including reducing the number of voids per day, leakage episodes and severity/degree of urgency. Case series data supported the effectiveness of SNS in this population to a maximum follow-up of 60 months.

Non-obstructive urinary retention

One randomised controlled trial comparing SNS to standard medical management showed SNS to be effective in this population. The treatment group displayed significant reductions in all measured catheterisation variables. Evidence from case series data was consistently supportive of the positive treatment effects of SNS. Durability was evaluated up to 70 months, with treatment effectiveness maintained. <u>Painful bladder syndrome</u>

The limited evidence base available for SNS in this population indicated positive treatment effects from SNS in the short-term, but has precluded definitive short- or long-term effectiveness conclusions for this population.

# Cost Effectiveness:

# Detrusor overactivity

Using years of complete dryness as the primary outcome measure, the cost per patient per year of additional dryness was estimated to be \$9,866. This was robust to univariate sensitivity analysis.

#### Non-obstructive urinary retention

For this indication, a successful result was defined as either a) elimination of catheterisation or b) at least a 50 per cent reduction in catheter volume per catheterisation. The cost per year over the seven year time horizon of these successful results was estimated to be \$7,129. This was robust to univariate sensitivity analysis. Painful bladder syndrome

As there was no clinical evidence for painful bladder syndrome which could be used in an economic evaluation, a costing analysis was undertaken. The incremental cost associated with SNS in this population was \$11,300 per patient.

#### Financial implications

It is estimated that 200 people per year will be eligible for SNS. Expert clinical opinion suggests that 90 per cent of patients would present with detrusor overactivity and 10 per cent with non-obstructive urinary retention. Should this be the case, the total net cost would be \$2.481 million per annum. This consists of costs incurred by the healthcare system, which sum to \$2.600 million, minus the cost reduction associated with reduced use of disposables by the individual (\$119,000).

#### Advice:

MSAC has considered the safety, effectiveness and cost-effectiveness of sacral nerve stimulation for urinary indications compared with clinical non-surgical management.

MSAC finds there is evidence for the safety of sacral nerve stimulation in adults with detrusor overactivity, non-obstructive urinary retention and painful bladder syndrome refractory to conservative, non-surgical intervention.

MSAC finds sacral nerve stimulation in adults with detrusor overactivity and nonobstructive urinary retention refractory to conservative, non-surgical intervention is more expensive than, but more effective than clinical non-surgical management. MSAC finds there is insufficient evidence to assess the effectiveness of sacral nerve stimulation in adults with painful bladder syndrome refractory to conservative, nonsurgical intervention.

MSAC recognises the social and quality of life issues associated with these conditions.

MSAC advises that public funding should be supported for the procedure of sacral nerve stimulation in adults with detrusor overactivity and non-obstructive urinary retention refractory to conservative, non-surgical intervention. MSAC advises that public funding should not be supported for the use of sacral nerve stimulation for treatment of patients with painful bladder syndrome.

The Minister for Health and Ageing noted MSAC's advice on 08 December 2008.

#### **Methods:**

The evidence regarding SNS for urinary indications was systematically assessed. Medline, EMBASE, Austhealth, CINAHL, PubMed and Science Citation Index and the Cochrane Library were searched for relevant literature from January 2000 to 15 January 2008.