NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

Axonics sacral neuromodulation system for bladder control in people with symptoms of overactive bladder

1 Technology

1.1 Description of the technology

The Axonics sacral neuromodulation (SNM) system (Axonics Modulation Technologies, Inc.), delivers sacral nerve stimulation therapy through a stimulator implanted subcutaneously in the upper buttock.

The stimulator generates electric pulses and is designed to operate on constant current which allows automatic adjustment of stimulation current. Lead electrodes implanted through corresponding sacral foramen transmit these pulses from the stimulator to the sacral nerves that control the bladder. The stimulator is powered by a rechargeable battery with an expected life span of at least 15 years, which is claimed to be longer than comparator non-rechargeable SNM devices. The device is programmed by a clinician.

A handheld remote control activates the stimulator, adjusts the stimulation amplitude, and checks the battery status. A wireless charger, attachable to the skin over the implanted stimulator is used to charge the stimulator. It is claimed that the battery needs a recharge every 1-2 weeks for 30 minutes to 1 hour.

Before permanent implantation, a trial is done for a few weeks to evaluate the efficacy of therapy in improving symptoms. The trial involves inserting a thin temporary wire near the sacral nerves in the lower back. The wire is connected to an external stimulator which sends stimulation to the nerves. A bladder diary is used before and after the procedure to assess improvement in

symptoms. Axonics SNM is MRI compatible and is claimed to be smaller than existing non-rechargeable SNM devices.

NICE has published a Medtech innovation briefing on this technology.

1.2 Relevant diseases and conditions

The Axonics SNM system is intended for use in the treating symptoms of overactive bladder, specifically in people for whom conservative therapy and drug treatment have failed or are not suitable.

The bladder and urethra are parts of the lower urinary tract which store and expel urine. These activities are regulated by both the central and peripheral nervous systems. Lower urinary tract symptoms have several causes including overactive bladder syndrome of unknown origin or other functional bladder disorders.

Lower urinary tract dysfunction may relate to impaired urine storage and /or bladder emptying resulting in symptoms such as overactive bladder syndrome (including urinary urge incontinence and/or symptoms of urgency-frequency). Urinary urge incontinence is a strong urge to urinate which is followed by an involuntary loss of urine. People who have urinary urge incontinence may also experience urgency-frequency (a need to pass urine more frequently than usual).

It is estimated that the prevalence of overactive bladder in the UK is 19% (Milsom et al. 2002).

1.3 Current management

NICE's guidelines on urinary incontinence and pelvic organ prolapse in women and lower urinary tract symptoms in men recommend initial management of symptoms with conservative methods (such as lifestyle interventions, behavioural techniques and physical therapies) or drug treatment. When conservative methods and drug treatment fail, investigation to assess detrusor overactivity is recommended. If detrusor overactivity exists, botulinum toxin type A can be injected into the bladder wall. The use of

botulinum injection may be associated with a need for clean intermittent catherisation or the use of temporary indwelling catheters.

If a patient is unwilling to accept the possible risk of catherisation with botulinum injection or if botulinum injection fails, NICE guideline recommends that, percutaneous sacral nerve stimulation should be offered[1]. NICE's interventional procedures guidance on sacral nerve stimulation for urge incontinence and urgency-frequency also suggests SNM is an option for people who have not responded to conservative management or drug treatment. Alternative invasive treatment options include bladder reconstruction (augmentation cytoplasty) and urinary diversion[2].

SNM involves applying an electric current to the sacral nerve believed to be responsible for communication between the bladder and the brain.

1.4 Regulatory status

The Axonics SNM system received a CE mark as a class III medical device in June 2016 for the treatment of urinary retention, symptoms of overactive bladder and chronic faecal incontinence

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Reduced number of repeat surgeries to replace the device and a reduction in the associated risks.
- Reduced pain and discomfort given the smaller size of the implant compared to previous similar devices.
- More time in optimal therapy range due to automatic adjustment of the therapy.
- Improved user experience.

[1] NICE NG123 Urinary incontinence and pelvic organ prolapse in women: management
[2] NICE NG123 Urinary incontinence and pelvic organ prolapse in women: management

The benefits to the healthcare system claimed by the sponsor are:

- Reduced number of surgical interventions
- Reduced cost of therapy

2 Statement of the decision problem

Population	People with symptoms of overactive bladder for whom conservative therapy and drug treatment have failed or are not suitable.
Intervention	Axonics Sacral Neuromodulation System
Comparator(s)	• Other sacral neuromodulation systems
Outcomes	The outcome measures to consider include: Primary outcomes • Responder rate (% of patients who experience 50% or more reduction in their leaks compared to baseline) • Level of reduction in overactive bladder symptoms such as average daily number of urgency leaks • The number of surgical interventions to replace SNM devices and the risks associated with these procedures • Time to battery depletion • Ease of use of device • Procedure related infection rates • Incidence of therapeutic failure • Improvement in quality of life including pain and discomfort Secondary outcomes • Explantation rate due to MRI • Time to revision surgery • Level of patient and carer satisfaction • Device-related adverse events
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which may include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	Slim people with lower than average BMI and a paucity of subcutaneous buttock fat are likely to benefit from a smaller device.

Special considerations, including those related to equality	Urinary incontinence is associated with the protected characteristics of age, disability, sex and pregnancy. The device is contraindicated in people who cannot operate the device, which could include people with physical or cognitive impairment.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Not applicable.	

3 Related NICE guidance

Published

- NICE guideline 123 (2019). Urinary incontinence and pelvic organ prolapse in women: management.
- NICE interventional procedures guidance 536 (2015 currently being updated). Sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention.
- NICE clinical guideline 97 (2010 updated 2015). Lower urinary tract symptoms in men: management.
- NICE interventional procedures guidance 64 (2004). Sacral nerve stimulation for urge incontinence and urgency-frequency.
- NICE clinical guideline 148 (2012). Urinary incontinence in neurological disease: assessment and management

4 External organisations

4.1 Professional organisations

The following societies have been alerted to the availability of the draft scope for comment:

- British Society of Urogynaecology
- British Association of Urological Surgeons
- Neuromodulation Society of the United Kingdom and Ireland
- British Association of Spinal Cord Injury Specialists

4.2 Patient organisations

NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment.

- Bladder and Bowel UK
- Bladder Health UK
- ERIC, The Children's Bowel & Bladder Charity
- International Children's Continence Society
- Urostomy Association
- Urology User Group Coalition