NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

Peristeen anal irrigation system to manage bowel dysfunction

1 Technology

Peristeen is a transanal irrigation system that is usually self-administered while sitting on a standard toilet, commode or shower chair. It comprises a rectal catheter with inflatable balloon, a manual control unit with pump, leg straps and a bag to hold water. Peristeen is claimed to be ergonomically designed for people with limited mobility; the pump has large switches and the balloon catheter means that the irrigation tube does not need to be held in place. Peristeen is intended for use by all people with bowel dysfunction but primarily those with neurogenic bowel dysfunction. It is used every 2 days or so to empty the rectum and distal sigmoid and prevent unexpected bowel movements or to prevent and relieve constipation.

1.1 Regulatory status

Peristeen received a CE mark in May 2003 as a class 1 medical device for transanal irrigation.

1.2 Claimed benefits

The benefits to patients claimed by the company are:

- Improves symptoms/reduces the severity of chronic constipation
- Reduces the severity and frequency of faecal incontinence
- Improves quality of life for people with bowel dysfunction
- Reduces the incidence of urinary tract infections (UTI) in patients with neurogenic bowel dysfunction.

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

- Reduces the rate of stoma surgery in patients with neurogenic bowel dysfunction
- Reduces the frequency and therefore the treatment costs of urinary tract infections
- Reduces the cost of treating neurogenic bowel dysfunction in people who have experienced unsuccessful standard bowel care as first line treatment
- Reduces the rate of hospitalisation in people with neurogenic bowel dysfunction.

1.4 Relevant diseases and conditions

Peristeen is used for transanal irrigation, specifically for people with bowel dysfunction such as neurogenic bowel dysfunction.

Neurogenic bowel dysfunction can be caused by neurological conditions such as spinal cord injury, spina bifida, multiple sclerosis, Parkinson's disease and other conditions associated with impairment or loss of sphincter control and bowel mobility disorders. People with impaired co-ordination/weakness secondary to a neurological condition are more likely to require carer assistance during their bowel routine. Bowel dysfunction may also be caused by an injury (for example following childbirth), slow transit constipation (unrelated to childbirth), obstructed defaecation symptoms, metastatic spinal cord compression, and low anterior resection syndrome in people who have had treatment for rectal cancer (radiation to the pelvis and/or surgery).

1.5 Current management

Current treatment options for bowel dysfunction may include medication (oral drugs, suppositories and enemas), dietary advice and changes, physiotherapy and surgery. People with bowel dysfunction may also be offered training to help manage their symptoms at home, using biofeedback, bowel washouts and manual removal of faeces.

The NICE guideline on the management of faecal incontinence in adults states that healthcare professionals should explain to people with the

condition that a combination of management interventions is likely to be needed. People with faecal incontinence should be offered advice on a range of coping strategies and treatment options.

People with neurogenic bowel dysfunction should be offered a neurological bowel management programme. If bowel continence cannot be achieved by conservative lifestyle changes such as diet changes or medication, long-term management strategies should be offered. The guideline states that rectal irrigation may be suitable treatment option for such patients. It should be noted that Peristeen is not the only transanal irrigation system available and that some systems are significantly different in terms of design and use, e.g. no balloon catheter. The choices should be discussed by clinician and patient and a number of systems may be tried before a preferred device for anal irrigation is found. Surgery, comprising the fashioning of a colostomy or ileostomy may be required in some patients. Other surgical interventions include sacral nerve stimulation, sphincter repair, artificial sphincter, ventral mesh rectopexy for rectal intussusception.

2 Reasons for developing guidance on Peristeen for bowel dysfunction

The committee considered that there is evidence to support the claims that Peristeen could offer measurable benefits to patients with neurogenic bowel dysfunction as part of a personalised approach to bowel management. It considered that the benefits are likely to be particularly important to those patients for whom conventional medical treatment has been ineffective or impractical and who may then avoid the need for more invasive surgical therapy

The committee was advised that Peristeen may have a significant impact on the quality of life of individual patients with neurogenic bowel dysfunction leading to greater confidence and independence. The committee considered that there is evidence that Peristeen has the potential to offer cost savings to

the NHS, particularly through the possible avoidance of more invasive treatment options.

3 Statement of the decision problem

	Draft scope issued by NICE
Population	People with bowel dysfunction in any setting.
Intervention	Peristeen anal irrigation system
Comparator(s)	Conservative bowel management, which can include: • diet and bowel habit advice • medication (oral drugs, suppositories and enemas) • disposable pads and anal plugs • muscle training/bowel retraining • biofeedback and electrostimulation • digital stimulation and manual evacuation It should be noted that the type of treatment a person receives is highly dependent on their personal preference, ability and the carer support available to them. (see also 'Cost analysis' below)
Outcomes	The outcome measures to consider include: • severity and frequency of incontinence and severity of constipation using appropriate scores (such as Cleveland clinic incontinence and constipation scores [also known as Wexner-incontinence and –constipation scores], St Mark's faecal incontinence score and neurogenic bowel dysfunction score) • quality of life • length and frequency of irrigation • device-related adverse events • frequency of urinary tract infection (UTI) • incidence of stoma surgery and hospitalisations • staff time including primary care and community care visits • individual length of use/user satisfaction
Cost analysis	Comparator(s): 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 will include carer costs, patient/carer training costs and costs of treating UTI.
Subgroups to be considered	• neurological bowel dysfunction complications for example Parkinson's disease, stroke, multiple sclerosis, spina bifida and spinal cord injury • bowel dysfunction caused by injury e.g. following childbirth • slow transit constipation (unrelated to childbirth) • obstructed defaecation symptoms • metastatic spinal cord compression

	• low anterior resection syndrome in people who have had treatment for rectal cancer	
Special considerations, including those related to equality	Faecal incontinence is a socially stigmatising condition, and if not managed properly can cause huge distress and can cause people to withdraw from society. People with faecal incontinence may require a carer, particularly if they have an underlying condition that affects their mobility. If bowel management is poor, carers may spend a lot of time cleaning and washing clothing. Some people may go without treatment or help if they are too embarrassed to speak to healthcare professionals or family and friends. Constipation causes pain and straining. If these symptoms cannot be resolved, constipation can lead to faecal impaction, bleeding, prolapse and bowel incontinence. If standard treatment fails, colostomy or ileostomy may be required. Constipation can also predispose to UTI since a full rectum may press on the bladder neck leading to incomplete emptying of the bladder and urinary retention.	
Special considerations, specifically related to equality issues	Peristeen is not suitable for children under 3 years of age, for use during the first 3 months following anal or colorectal surgery or for people with the following conditions: anal or colorectal stenosis, colorectal cancer, acute inflammatory bowel disease, acute diverticulitis and ischaemic colitis. Peristeen is not suitable for people with bowel routines that must take place on a bed.	
	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

4 Related NICE guidance

Published

- Irritable bowel syndrome in adults: diagnosis and management (2015) NICE guideline 61
- Multiple sclerosis in adults: management (2014) NICE guideline 186
- Stroke rehabilitation in adults (2013) NICE guideline CG162
- Autism spectrum disorder in under 19s: recognition, referral and diagnosis (2011) NICE guideline CG128

- Constipation in children and young people: diagnosis and management (2010) NICE guideline CG99
- Rehabilitation after critical illness in adults (2009) NICE guideline CG83
- Metastatic spinal cord compression in adults: diagnosis and management (2008) NICE guideline CG75
- Faecal incontinence in adults: management (2007) NICE guideline CG49

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Academy of Medical Royal Colleges
- Academy of Medical Sciences
- Royal College of General Practitioners
- The Family Doctor Association
- National Association of Primary Care
- Royal College of Nursing
- Association of British Neurologists
- Association of Coloproctology of Great Britain and Ireland (ACPGBI)
- Association of Upper Gastrointestinal Surgeons of Gt. Britain & Ireland (AUGIS)
- British Geriatrics Society
- British Paediatric Neurology Association
- British Society of Gastroenterology
- British Society of Paediatric Gastroenterology, Hepatology and Nutrition
- Royal College of Paediatrics and Child Health

5.1.2 Professional organisations invited to comment on the draft scope

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

- Academy of Medical Royal Colleges
- Academy of Medical Sciences
- Royal College of General Practitioners
- The Family Doctor Association
- National Association of Primary Care
- Royal College of Nursing
- Association of British Neurologists
- Association of Coloproctology of Great Britain and Ireland (ACPGBI)
- Association of Upper Gastrointestinal Surgeons of Gt. Britain & Ireland (AUGIS)
- British Geriatrics Society
- British Paediatric Neurology Association
- British Society of Gastroenterology
- British Society of Paediatric Gastroenterology, Hepatology and Nutrition
- Royal College of Paediatrics and Child Health

5.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Action Cerebral Palsy
- Aspire
- Brain and Spinal Injury Charity
- Brain and Spine Foundation (UK)
- Brain Injury Rehabilitation Trust
- Cerebra
- Crohn's and Colitis UK

- The Cure Parkinsons Trust
- forCrohns
- Headway - The Brain Injury Association
- Huntingtons Disease Association
- Motor Neurone Disease Association
- Multiple Sclerosis Society
- Multiple Sclerosis Trust
- Multiple Sclerosis-UK
- Parkinson’s UK
- Progressive Supranuclear Palsy Association
- Promocon
- Scope
- Shine
- Short Bowel Survivors and Friends
- Spinal Injuries Association
- The Ann Conroy Trust
- The Neuro Foundation
- The Neurological Alliance
- Transverse Myelitis Society