

Commissioning Statement

Treatment/ device	Trans-anal Irrigation Systems These include: <ul style="list-style-type: none">• Peristeen[®] (Coloplast Ltd)• Qufora[®] (MacGregor Healthcare Ltd)• Aquaflush[®] (Oakmed Ltd)• IryPump S[®] (B Braun Medical)• Navina Smart[®] (Wellspect Healthcare)
For the treatment of	<ul style="list-style-type: none">• Neurogenic bowel dysfunction, e.g. spinal cord injury, spina bifida, multiple sclerosis• Chronic constipation, including both evacuation difficulties and slow transit constipation• Chronic faecal incontinence
Commissioning position	<p>XXXX CCG commissions the use of rectal irrigation systems for the management of chronic constipation and/or chronic faecal incontinence, including that due to neurogenic bowel dysfunction. Rectal irrigation should only be considered where all other less invasive methods of bowel management have proved unsuccessful to adequately control constipation and/or faecal incontinence. Initial management may include:</p> <ul style="list-style-type: none">• dietary measures;• adjusting fluid intake;• bowel habit;• ensuring toilet access;• evacuation techniques;• medication;• coping strategies. <p>Rectal irrigation is a highly specialist management option and therefore:</p> <ul style="list-style-type: none">• the patient should be referred to a specialist service for a specialist assessment (GP practices will not be expected to initiate prescribing without specialist management of the patient);• the initial supply is made from specialist services;• appropriate communication has been made to the GP (i.e. product name, frequency of use, when specialist service will review patient, description according to entry in the Drug Tariff; PIP codes to be supplied if known). <p>North Kirklees CCG/Bradford City CCG/Bradford Districts CCG/Greater Huddersfield CCG/Wakefield CCG/Calderdale CCG</p>

Date effective from	29.05.2018
Policy to be reviewed by	28.05.2021 (to be reviewed earlier if NICE issues guidance at an earlier date)
Background information	<p>Trans-anal irrigation (TAI) is reported to benefit some patients with faecal incontinence, rectocele (rectal prolapse) and constipation [1,2]. It is possibly more effective in patients with passive soiling than those with urge incontinence secondary to loose stool [3]. It has been more widely reported in children with spina bifida than in adults [4,5,6].</p> <p>TAI has been found in a small randomised controlled trial to be effective for both constipation and faecal incontinence in people with spinal cord injury [7]. In a scintigraphic study (n=19), anal irrigation was found to empty stool as far up as the splenic flexure [8].</p> <p>The Royal College of Surgeons of England has published a commissioning guide about faecal incontinence. This states that anal irrigation is part of a range of treatment modalities considered following full assessment of the patient [9].</p> <p>TIA is one of the options in the NICE clinical guideline on managing faecal incontinence in adults [10].</p> <p>NICE guidance on the diagnosis and management of idiopathic constipation in children and young people does not include TIA as a treatment option prior to surgical intervention [11].</p>
Summary of evidence/ rationale	<p>There is a relatively small evidence base for this procedure at present.</p> <p>The only indication for which there is prospective, randomised controlled trial evidence (from one study) supporting rectal irrigation is spinal cord injury with neurogenic bowel dysfunction in adults (n=87) [7]. For other indications, data are largely derived from uncontrolled studies or case series.</p> <p>Rectal irrigation will usually only be tried if other less invasive methods of bowel management have failed to adequately control constipation and/or faecal incontinence. Depending on each individual's assessed symptoms and need, options for patients include [10]:</p> <ul style="list-style-type: none"> • dietary measures; • bowel re-training; • biofeedback; • electrical stimulation; • pelvic floor muscle training. <p>Mild and transient side effects including abdominal pain, chills, nausea, minor rectal bleeding occur in about 40 to 75% of patients. There is a potential for autonomic dysreflexia, a particular concern for patients with spinal cord injury with lesions located at T6 or above [12].</p> <p>Patients will need support from the Bladder and Bowel Service (colorectal</p>

*Updated May 2018 following new NICE Guidance on Peristeen trans-anal irrigation system for managing bowel dysfunction

	<p>service) when they initially use the system. A medical evaluation by an appropriate specialist is necessary before starting treatment [13].</p> <p>Comprehensive training, plus ongoing support for the patient is essential for safe and efficient long term use of rectal irrigation. Patients should be taught to recognise the symptoms of colonic perforation, an extremely rare side effect, and what actions to take [14].</p> <p>Consider using a validated scoring system at baseline and reviews to aid assessment of continued need. Re-evaluation is necessary if success has not been attained by 8 to 12 weeks. On-going treatment should be reviewed regularly [13].</p> <p>It is not known if one system out-performs another [13]. A randomised trial is currently comparing low-volume and low-volume anal irrigation in adults with chronic constipation [15]. Quality of life is being assessed after 3 month's treatment.</p> <p>Cost effectiveness/resource impact:</p> <p>In a study of 227 patients with neurogenic bowel dysfunction who had failed on conservative bowel management, treatment with Peristeen® resulted in improved bowel scores, less faecal incontinence episodes, fewer urinary tract infections and less use of healthcare resources such as hospitalisations and visits to the doctor. A health economic model predicted average life-long savings for the NHS of £21,768 per patient, compared to not initiating the patient on Peristeen® [16, 17].</p> <p>References</p> <ol style="list-style-type: none"> 1. Gardiner A et al. Rectal irrigation for relief of functional bowel disorders. <i>Nursing Standard</i> 2004;19(9):39-42 2. Crawshaw AP et al. A retrospective evaluation of rectal irrigation in the treatment of disorders of faecal continence. <i>Colorectal Disease</i> 2004;6(3):185-90 3. Briel JW et al. Clinical value of colonic irrigation in patients with continence disturbances. <i>Diseases of the Colon & Rectum</i> 1997; 40(7):802-5 4. Liptak GS & Revell GM. Management of bowel dysfunction in children with spinal cord disease or injury by means of the enema continence catheter. <i>Journal of Paediatrics</i> 1992;120(2):190-45. 5. Scholler-Gyure M et al. Treatment of defecation disorders by colonic enemas in children with spina bifida. <i>European Journal of Paediatric Surgery</i> 1996;6:32-4 6. Shandling B & Gilmour RF. The enema continence catheter in spina bifida: successful bowel management. <i>Journal of Pediatric Surgery</i> 1987;22(3):271-3 7. Christensen P et al. A Randomized, Controlled Trial of Transanal Irrigation Versus Conservative Bowel Management in Spinal Cord-Injured Patients. <i>Gastroenterology</i> 2006;131(3):738-47 8. Christensen P et al. Scintigraphic Assessment of Retrograde Colonic Washout in Fecal Incontinence and Constipation. <i>Diseases of the Colon & Rectum</i> 2003;46(1):68-76
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	<p>9. Royal College of Surgeons and the Association of Coloproctology of Great Britain and Ireland. Commissioning guide: Faecal incontinence. January 2014, revised November 2014. Accessed from https://www.rcseng.ac.uk/library-and-publications/college-publications/docs/faecal-incontinence-guide/ on 21.7.2017</p> <p>10. NICE. Clinical Guideline 49. Faecal incontinence in adults: management. 27 July 2007. Accessed from https://www.nice.org.uk/guidance/cg49/resources/faecal-incontinence-in-adults-management-pdf-975455422405 on 4.4.2017</p> <p>11. NICE. Clinical Guideline 99. Constipation in children and young people: diagnosis and management. 26 May 2010 (last updated July 2017). Accessed from https://www.nice.org.uk/guidance/cg99/resources/constipation-in-children-and-young-people-diagnosis-and-management-pdf-975757753285 on 4.4.2017</p> <p>12. Christensen P & Krogh K. Transanal irrigation for disordered defecation: A systematic review. Scandinavian Journal of Gastroenterology 2010;45:517-27</p> <p>13. PrescQIPP. Bulletin 171 Rectal Irrigation. February 2017. Accessed from https://www.prescgipp.info/rectal-irrigation/category/348-rectal-irrigation-drop-list on 4.4.2017</p> <p>14. Emmanuel A et al. Consensus review of best practice of transanal irrigation in adults. Spinal Cord 2013;51:732-738</p> <p>15. ISRCTN Registry. CapaCiTY Study 2 - Chronic Constipation Treatment Pathway. Accessed from http://www.isrctn.com/ISRCTN11093872?q=anal%20irrigation&filters=&sort=&offset=1&totalResults=3&page=1&pageSize=10&searchType=basic-search on 21.7.2017</p> <p>16. Emmanuel A et al. Long-Term Cost-Effectiveness of Transanal Irrigation in Patients with Neurogenic Bowel Dysfunction. PLOS ONE 11(8): e0159394. doi:10.1371/journal.pone.0159394</p> <p>17. NICE Medical Technologies Guideline 36: Peristeen trans-anal irrigation system for managing bowel dysfunction. Published February 2018 Accessed from: https://www.nice.org.uk/guidance/mtg36</p>
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*Updated May 2018 following new NICE Guidance on Peristeen trans-anal irrigation system for managing bowel dysfunction