

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	Updated 15 th November 2022
Appraisal & Details	<p>Transanal irrigation (TAI) systems (Peristeen Plus®, Aquaflush®, and QuFora®) for neurogenic bowel dysfunction, chronic constipation and chronic faecal incontinence.</p> <p>The Northern (NHS) Treatment Advisory Group considered an appraisal of transanal irrigation systems for the treatment of chronic constipation, chronic faecal incontinence and neurogenic bowel dysfunction.</p> <p>(updated November 2022 as Irypump® S discontinued)</p>
Recommendation	<p>The Northern (NHS) Treatment Advisory Group recommends the use of transanal irrigation as an option for treatment when all other treatment options have failed or proved ineffective and if initiated and monitored by a specialist.</p> <p>This is in line with the NICE clinical guideline for the management of faecal incontinence, NICE MTG 36 Peristeen transanal irrigation system for managing-bowel-dysfunction, the Royal College of Surgeons clinical commissioning guide and the European Consensus review.</p> <p>It was agreed that taking into account any patient factors it would seem reasonable to use the system with the lowest acquisition cost first.</p>
Clinical evidence summary	<p>A transanal irrigation system (also known as rectal irrigation) refers to the introduction of water (or other solution) into the rectum and left colon via the anus. The group noted that there is a reasonable volume of evidence for TAI in neurogenic bowel dysfunction however the majority of it is low quality (non-randomised studies, no control groups, small patient numbers etc.) however robust randomised trials are difficult to design and undertake given the invasive nature of TAI adequate blinding is virtually impossible and placebo interventions may be problematic. Efficacy was assessed in a Cochrane review, the review included one small (n=87) 10 week randomised trial which had a small risk of bias. Participants used the Peristeen® system daily or every other day in addition to conservative bowel care or conservative bowel care alone. Statistically significant constipation, neurogenic bowel disease and faecal incontinence sores were found in the TAI group compared to the conservative group. TAI also resulted in a significantly reduced time for bowel care and increased satisfaction.</p> <p>Whilst there have been several cost effectiveness analyses presented at conferences, there are no fully published, independent economic assessments of TAI in the medical literature.</p>
Safety	<p>TAI is generally considered a safe procedure providing users are adequately trained in its use. The most serious risk is that of bowel perforation which can be potentially fatal. The MHRA has issued a medical device alert reminding healthcare professionals to ensure that patients and carers:</p> <ul style="list-style-type: none"> • Have received comprehensive training and are competent in the use of the system before using it unsupervised • Are aware of the risk of bowel perforation, how to recognise the symptoms, and action to be taken.
Patient Perspective	<p>Chronic constipation and faecal incontinence can be associated with a dramatic decrease in quality of life affecting both physical and mental health. Patients will be pleased that TAI offer a potential option when other options have failed or been ineffective.</p>

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<p>Cost analysis summary</p>	<p>Costs will be dependent on the system selected and how often they are used. The table below shows the current (<i>Drug Tariff, November 2022</i>) cost of some of TAI systems available.</p> <table border="1" data-bbox="451 479 1476 1496"> <thead> <tr> <th>Product</th> <th>Starter Pack cost</th> <th>Maintenance pack cost (based on 15 irrigations per month)</th> <th>Cost per year (based on 15 irrigations per month, incl. starter pack)</th> </tr> </thead> <tbody> <tr> <td>Aquaflush® Compact Plus</td> <td>£34.84 (Once only)</td> <td>£59.53</td> <td>£749.20</td> </tr> <tr> <td>Aquaflush® Compact</td> <td>£34.84 (Once only)</td> <td>£59.53</td> <td>£749.20</td> </tr> <tr> <td>Aquaflush® Lite</td> <td>£74.93</td> <td>£97.51 <i>Note; monthly product is for 16 devices, as cannot split have assumed one product per month</i></td> <td>£1245.05</td> </tr> <tr> <td>Peristeen Plus® (all sizes)</td> <td>£80.44 every 6 months As "System" (Small or Regular, with Control Unit)</td> <td>£140.20 For accessory unit (Small or Regular) with 15 rectal catheters</td> <td>£1843.28</td> </tr> <tr> <td>Qufora IrriSedo® MiniGO</td> <td>n/a</td> <td>£97.50 (€195.00 per 30-irrigation set)</td> <td>£1170.00</td> </tr> <tr> <td>Qufora IrriSedo® Klick</td> <td>£89.09 (Once only)</td> <td>Control unit 1 per 6 months = £51.11 Catheter set = £135.28 per month</td> <td>£1814.67</td> </tr> <tr> <td>QuFora IrriSedo® Cone</td> <td>£80.72 (Once only)</td> <td>£105.48</td> <td>£1346.48</td> </tr> </tbody> </table> <p>Additional costs may be incurred for routine maintenance/ replacement of parts, as well as optional accessories such as additional tubing or leg straps. A supply of wipes and disposal bags should also be dispensed alongside equipment. As well as the directly chargeable equipment costs, patient and carer training will incur an additional cost.</p>	Product	Starter Pack cost	Maintenance pack cost (based on 15 irrigations per month)	Cost per year (based on 15 irrigations per month, incl. starter pack)	Aquaflush® Compact Plus	£34.84 (Once only)	£59.53	£749.20	Aquaflush® Compact	£34.84 (Once only)	£59.53	£749.20	Aquaflush® Lite	£74.93	£97.51 <i>Note; monthly product is for 16 devices, as cannot split have assumed one product per month</i>	£1245.05	Peristeen Plus® (all sizes)	£80.44 every 6 months As "System" (Small or Regular, with Control Unit)	£140.20 For accessory unit (Small or Regular) with 15 rectal catheters	£1843.28	Qufora IrriSedo® MiniGO	n/a	£97.50 (€195.00 per 30-irrigation set)	£1170.00	Qufora IrriSedo® Klick	£89.09 (Once only)	Control unit 1 per 6 months = £51.11 Catheter set = £135.28 per month	£1814.67	QuFora IrriSedo® Cone	£80.72 (Once only)	£105.48	£1346.48
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<p>Financial impact</p>	<p>There is no robust information on how many patients would be eligible for TAI however total numbers are thought to be small. TAI systems are already prescribed by GP's across North East and Cumbria.</p>																																
<p>PbR: In-tariff</p>	<p>A reduction in bowel dysfunction symptoms may lead to decreased healthcare costs, but there is currently no reliable evidence of this.</p>																																