

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	2 nd June 2020
Appraisal & Details	The Northern (NHS) Treatment Advisory Group considered an appraisal of Purewick® female external urinary catheter for the management of female urinary incontinence.
Recommendation	<p>The Northern (NHS) Treatment Advisory Group <u>does not</u> recommend the use of Purewick® female external urinary catheter for the management of female urinary incontinence.</p> <p>Purewick® is the first female external catheter to address the need for an effective, non-invasive method of managing urine output in women. It is an alternative to incontinence pads and indwelling catheters for female patients with urinary incontinence. An application for inclusion within the Drug Tariff to enable prescribing on FP10 is currently pending, and a decision is not expected before the end of 2020.</p> <p>The group was concerned about the lack of published clinical evidence and that evidence to support this comes largely from unpublished individual hospital evaluations of the product. The Purewick® External Female Catheter may offer some advantages in terms of patient acceptability and quality of life but good quality clinical trial data to support long-term clinical effectiveness and cost-effectiveness is lacking.</p> <p>After discussion NTAG agreed not to recommend use of Purewick® on the NHS because currently there is a lack of quality published clinical evidence to support the efficacy of this device at this time. NTAG agreed to review this recommendation if and when further evidence becomes available, and to suggest to the CCGs that they may wish to work with the manufacturer to evaluate the product further in a local product evaluation/trial.</p>
Clinical evidence summary	<p>Currently evaluation data for the device is only available in conference abstracts/posters or unpublished evaluations carried out by individual hospitals. A Medline and Embase search found no trials that had been fully published and only two published conference abstracts. As yet there is no good quality published clinical evidence which directly compares the Purewick® External Female Catheter with indwelling catheters or incontinence pads. There is also currently no NICE guidance available on or which includes the use of the Purewick® device.</p> <p>Purewick® may help to reduce urinary catheter days thus lowering the risk of Catheter Associated Urinary Tract Infection (CAUTIs). It was agreed any reduction in CAUTIs would be a benefit. It also may help reduce the risk of moisture lesions/skin irritation from incontinence pads, and therefore reduce the associated risk of pressure ulcer damage by wicking away urine from the body. Published data including these outcomes is, however, not currently available.</p>
Safety	<p>The long term safety and benefit of Purewick® is unknown and there is no published safety data available on the use of the Purewick®.</p> <p>The Purewick® device should not be used for patients with urinary retention or in patients with a known latex allergy. It should also be used with caution in patients who have undergone recent surgery to the external urogenital tract.</p>

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<p>Patient Perspective</p>	<p>Purewick® is the first female external catheter to address the need for an effective, non-invasive method of managing urine output in women. It is an alternative to incontinence pads and indwelling catheters for female patients with urinary incontinence.</p> <p>Purewick® may help to reduce urinary catheter days thus lowering the risk of Catheter Associated Urinary Tract Infection (CAUTIs). It also may help reduce the risk of moisture lesions/skin irritation from incontinence pads, and therefore reduce the associated risk of pressure ulcer damage by wicking away urine from the body.</p> <p>Purewick® is available to purchase by patients online should they wish to try the device.</p>
<p>Cost analysis summary</p>	<p>There is no robust, published information on how many patients would be eligible for the Purewick® device in the NTAG region.</p> <p>According to NICE NG123 around 51% of women in England report symptoms of urinary incontinence, with 25% of women seeing a GP for symptoms. NICE estimated in 2019 from data provided by NHS supply chain, that around 141,000 women in England are currently receiving clinical commissioning group funded absorbent containment products.</p> <p>The cost of the device is as follows:</p> <ul style="list-style-type: none"> • Purewick® Catheter = £6 incl VAT for one = £6 -12 per day per patient • Purewick® Urine Collection System = £399 incl VAT • Accessory kit/Purewick® Collection Canister = £20 incl VAT every 60 days <p>The ongoing costs per patient are therefore £380 to £740 every 60 days:</p> <ul style="list-style-type: none"> • Purewick Catheter – up to 2 per day required = £180 - £360 per month • Purewick Accessory Kit – replaced every 60 days = £20 <p>The portable pump (if required) is bought and owned by the organisation/patient purchasing it and if used 24 hours a day is a minimum life expectancy of 2 years.</p>
<p>Financial impact</p> <p>PbR: NA</p>	<p>The financial impact of this recommendation is expected to be nil.</p>