

# New Medicine Recommendation

## Navina Smart® trans-anal irrigation

### Recommendations

**Amber 0** for neurogenic bowel dysfunction

**Do not prescribe** for non-neurogenic bowel dysfunction

### Summary

- High quality clinical trials evidence is limited for trans-anal irrigation systems (TAIs), although NICE believe that the use of TAI is supported by the evidence base.
- TAIs are used in patient cohorts who may experience significant disability.
- There is cross border use of Navina Smart devices.
- According to costing by other ICBs/CSUs and available data for local spends on TAIs, the cost of Navina Smart is higher initially but the recurrent cost of consumables is unlikely to be significantly different to Peristeen Plus over the lifespan of the device.

### Background

Current treatment options for bowel dysfunction include medication (oral drugs, suppositories, and enemas), changes to diet, 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. [1]

Trans-anal Irrigation Systems (TAIs) are a method used to empty the bowel of faeces (up to the splenic flexure) using warm water which is introduced with a catheter via the anus into the rectum. The water and contents of the descending colon, sigmoid colon and rectum are then evacuated. Regular and controlled evacuation in this manner aims to prevent both constipation and faecal soiling.

The LSCMMG has a position statement recommending the use of TAIs in Neurogenic Bowel Dysfunction and Non-Neurogenic Bowel Dysfunction including; chronic constipation and chronic faecal incontinence (Amber0). The position statement is available at <https://www.lancsmmg.nhs.uk/media/1185/trans-anal-irrigation-devices-position-statement-v13.pdf>.

Within the position statement document, brands of TAIs are referenced e.g. Qufora, Aquaflush, Peristeen.

The Navina Smart Irrigation system is the only product on the market providing software-controlled pumps to inflate balloons and instil water into the bowel. The manufacturer states that “Navina Smart comes with an app that allows patients to track and record their settings and progress, so that they can optimise their routine. All data from the patient’s latest irrigation, such as balloon size, amount of water, waterflow rate and duration time, can be transmitted to the Navina Smart app via Bluetooth.” [2]

## **Innovation, need and equity**

Navina Smart differs from existing TAIs due to the ability to electronically control irrigation with the aid of an app. The Navina Smart app also enables the patient to share their data with health care professionals for evaluating treatment. [2]

As TAIs are used in patients with neurogenic conditions, there may be a cohort of patients with dexterity issues who would benefit from a non-manual TAIs.

## **Safety and efficacy evidence**

### NICE MTG for Peristeen Plus

NICE has issued the following guidance relating to the use of the Peristeen trans-anal irrigation system [1]:

- The case for adopting Peristeen for trans-anal irrigation in people with bowel dysfunction is supported by the evidence. Peristeen can reduce the severity of constipation and incontinence, improve quality of life, and promote dignity and independence.

Although the NICE medical technology guideline relates specifically to the Peristeen trans-anal irrigation system NICE advise that:

*“...If bowel continence cannot be achieved by medication, changes to diet and physiotherapy and long-term management strategies such as transanal irrigation should be considered. A number of different transanal irrigation systems, including Peristeen, are available. Clinicians and patients should discuss the options available and may try a number of devices before settling on a preferred system...”*

### Evidence for Navina Smart

There is limited evidence for the use of TAIs. According to a systematic review the highest evidence of TAI improving bowel function and QoL is from three RCTs showing superiority of TAI over best supportive care. [3] There are no comparative studies for the different TAIs, therefore preference is driven by patient preferences and tolerability.

There are no randomised controlled trials for Navina Smart. Short term efficacy and safety data is available from an open, prospective efficacy study on Navina Smart, in individuals with neurogenic bowel dysfunction secondary to spinal cord injury, studied at three months. [4] This study demonstrated improvements in symptom measures especially for patients judged to have severe symptoms at baseline. Side effects possibly related to the device developed in eleven subjects (12%). Discontinuation due to failure of therapy to relieve symptoms was reported by five subjects (6%).

## **Cross border issues**

Both Pan Mersey and GMMMG have produced commissioned positions supporting the use of TAIs.

GMMMG does not have a specific position for TAIs with an electric pump.

Pan Mersey states the following:

*“Electric pumps such as Iry Pump and Electric Wellspect should only be used for patients that meet all the other criteria but have very poor dexterity e.g. as a result of spinal injury, MS or CVA and are unable to use a balloon pump.”*

### Financial implications

When reviewing the budgetary impact of Peristeen Plus, NICE concluded the following:

*“Cost modelling for Peristeen Plus is uncertain, but it is likely that Peristeen Plus provides additional clinical benefits without costing more than standard bowel care.”*

Cost comparisons between different TAIs suggest that the recurring monthly cost of Peristeen Plus and Navina Smart are approximately equivalent, however the starter packs (with control unit) for Navina Smart cost approximately £310 every 2 years while Peristeen Plus starter packs cost approximately £80 every 6 months.

### Service impact implications

Treatment should be initiated and stabilised by specialist service providers for a period of 3 months. Prescribing responsibilities may then be transferred to primary care after the initial 3-month period only where there has been a demonstrable improvement in validated measures of bowel function such as the Cleveland Clinic constipation scoring system, St Mark’s faecal incontinence score or neurogenic bowel dysfunction score.

TAI is only supported by the LSCMMG in the context of an agreed commissioning pathway. Specialist services are expected to retain responsibility for on-going patient follow-up and review (until such time that treatment is stopped).

### References

- [1] NICE, “Peristeen Plus transanal irrigation system for managing bowel dysfunction MTG36,” June 2022. [Online]. Available: <https://www.nice.org.uk/guidance/mtg36>. [Accessed May 2024].
- [2] Wellspect Healthcare, “Bowel products Navina Smart,” 2022. [Online]. Available: <https://www.wellspect.co.uk/products/bowel-products/navina-irrigation-system/navina-smart/>. [Accessed May 2024].
- [3] Mekhael M et al, “Transanal Irrigation for Neurogenic Bowel Disease, Low Anterior Resection Syndrome, Faecal Incontinence and Chronic Constipation: A Systematic Review,” *J Clin Med*, vol. 10, no. 4, p. 753, 2021.
- [4] Emmanuel A et al, “An open prospective study on the efficacy of Navina Smart, an electronic system for transanal irrigation, in neurogenic bowel dysfunction,” *PLoS ONE*, vol. 1, no. e0245453, p. 16, 2021.