

## Northern (NHS) Treatment Advisory Group

### Treatment Appraisal: Decision Summary

<b>Date</b>	2 <sup>nd</sup> June 2020 (updated 15 <sup>th</sup> November 2022)
<b>Appraisal &amp; Details</b>	The Northern (NHS) Treatment Advisory Group considered an appraisal of <b>Vaginal devices for female urinary stress incontinence.</b>
<b>Recommendation</b>	<p>The Northern (NHS) Treatment Advisory Group <b><u>does not</u></b> recommend the use of Vaginal devices (e.g. Diveen®, Contiform® and Efemia®) for the routine management of female urinary stress incontinence on the NHS as per NICE NG123</p> <p>But does recommend use as per NICE NG210: Pelvic floor dysfunction: prevention and non-surgical management:</p> <ul style="list-style-type: none"> <li>• For women who are unable to perform an effective pelvic floor muscle contraction, consider supplementing pelvic floor muscle training with biofeedback techniques, electrical stimulation or vaginal cones.</li> <li>• Consider a trial of intravaginal devices for women with urinary incontinence, only if other non-surgical options have been unsuccessful.</li> </ul> <p>The product should only be initiated by a specialist pelvic health physiotherapist and only continue if evidence of continued benefit.</p> <p>Diveen®, Contiform® and Efemia® are intravaginal devices usually similar to a tampon in shape and size. They are included in the Drug Tariff and are indicated for stress or mixed urinary incontinence. There are other similar devices which are not yet included in the Drug Tariff.</p>
<b>Clinical evidence summary</b>	<p>The place in therapy remains unclear due to limited evidence base and uncertainty surrounding the clinical importance of unpublished trial findings.</p> <p>Devices for stress urinary incontinence are not recommended by NICE in NG123: “Intravaginal devices should not be used for the routine management of urinary incontinence in women. These devices should not be considered other than for occasional use when necessary to prevent leakage, for example during physical exercise. This is because of limited evidence for these devices and adverse effects are common, these include urinary tract infections, vaginal irritation and voiding difficulties”.</p> <p>However Pelvic floor dysfunction: prevention and non-surgical management NICE guideline [NG210] Published: 09 December 2021 states that for additional therapies, such as weighted vaginal cones, biofeedback and electrical stimulation, the evidence was inconsistent. Some studies showed benefits, and others showed no effect. Some of the evidence suggested that these interventions could help women with pelvic floor muscle training by improving their ability to contract their pelvic floor muscles. In the committee’s experience, effective pelvic floor contractions and relaxations are important for improving pelvic floor dysfunction symptoms and most women are able to do this as part of a supervised pelvic floor muscle training programme. However, the committee believed that supplementing a pelvic floor muscle training programme with biofeedback, electrical stimulation or vaginal cones could be cost effective in the subgroup who make little progress during supervised pelvic floor muscle training. These</p>

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	<p>additional therapies are particularly likely to be cost effective if using them allows women to avoid the need for surgical intervention. Based on the limitations of the evidence and the potential complications, the committee recommended trialling intravaginal devices if other non-surgical options have been tried and have been unsuccessful, so that women could decide whether they were beneficial before using them long term.</p>																		
<b>Safety</b>	<p>The long-term safety and efficacy of these vaginal devices for female urinary stress incontinence is unknown.</p> <p>Adverse effects including urinary tract infections, metrorrhagia and residual urine have been reported.</p>																		
<b>Patient Perspective</b>	<p>Lifestyle advice such as reducing caffeine intake, weight loss and smoking cessation are considered first line treatments for stress urinary incontinence, followed by pelvic floor muscle training (PFMT). Most patients with stress incontinence can be treated successfully with these measures</p> <p>Intravaginal devices may be considered if these measures are not effective in managing symptoms and prior to considering more invasive treatments such as bladder neck injections or surgery. Patients should be encouraged to continue PFMT whilst using the devices. Use of an intravaginal insert is not the only route at this stage, some women may benefit from biofeedback or electrical stimulation before considering invasive treatments.</p>																		
<b>Cost analysis summary</b>	<p>The number of patients who would be suitable for an intravaginal device is unknown. But about 1-2 patients per month across the whole of North Cumbria at most. The devices do not last for ever and patients may well return to their GP for another prescription.</p> <p><u>Diveen®</u></p> <p>The device can be worn <u>twice</u> before it needs to be replaced.</p> <table border="1"> <thead> <tr> <th></th> <th>Cost</th> <th>Annual Cost (worn every day)</th> <th>Annual Cost (worn twice a w</th> </tr> </thead> <tbody> <tr> <td>15 devices (small / medium) + 1 applicator</td> <td>£41.17</td> <td>£494.04</td> <td>£164.68</td> </tr> </tbody> </table> <p><u>Contiform®</u></p> <p>The device can be worn <u>thirty</u> times before it needs to be replaced.</p> <table border="1"> <thead> <tr> <th></th> <th>Cost</th> <th>Annual Cost (worn every day)</th> <th>Annual Cost (worn twice a w</th> </tr> </thead> <tbody> <tr> <td>Starter Pack</td> <td>£51.56</td> <td rowspan="2">£344.56</td> <td rowspan="2">£131.48</td> </tr> <tr> <td>Replacement pessary (small / medium / large)</td> <td>£26.64</td> </tr> </tbody> </table> <p><u>Efemia®</u></p> <p>The device can be worn for <u>three months</u> before it needs to be replaced.</p>		Cost	Annual Cost (worn every day)	Annual Cost (worn twice a w	15 devices (small / medium) + 1 applicator	£41.17	£494.04	£164.68		Cost	Annual Cost (worn every day)	Annual Cost (worn twice a w	Starter Pack	£51.56	£344.56	£131.48	Replacement pessary (small / medium / large)	£26.64
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		Cost	Annual Cost (worn every day)	Annual Cost (worn twice a week)
	Pack	£49.00	£196	£196
	Prescribing data suggests in NENC Contiform is most commonly prescribed followed by Diveen. Efemia only prescribed in Northumberland.			
<b>Financial impact</b>	Approx one to two patients per sub- ICB per year.			
<b>PbR: NA</b>				