

Surrey Heartlands Integrated Care System Area Prescribing Committee (APC)

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North-West Surrey, and East Surrey Places & associated partner organisations.

Situation, Background, Assessment and Recommendations (SBAR) paper for APC

Intravaginal devices for urinary incontinence

Situation

In March 2023 the following holding statement was uploaded to the PAD for devices for female stress incontinence.

- Primary care prescribers are not expected to have the clinical expertise to prescribe these devices and should therefore not be asked to prescribe until a formal evaluation and recommendations have been submitted to the APC

Prior to the March 2023 PAD statement, a physiotherapist would send a letter to the GP requesting they consider a prescription for one of these devices. Since the change to the Surrey PAD there is some disparity across the area.

- Most patients with a GP in North-West Surrey are unable to gain these items via their GP on prescription. Currently patients in NWS are only able to access these products where particular GPs make exceptions to PAD or by purchasing them privately (as this not a prescription only device).
- Patients in SASH have the GP prescriptions filled without issue
- RSH patients are limited to one product only as sample (Contrelle) and then are obtaining a GP prescription for ongoing care. The Contrelle device is not the most cost-effective option and may not be suitable for all women.

All pelvic health physiotherapy teams across Surrey Heartlands have been consulted in this process change and are in support of this.

Unfortunately, there are no prescribers in the pelvic health physiotherapy team, the team works in community clinics and does not have access to any hospital prescribers / hospital pharmacy. Surrey Heartlands pelvic physiotherapy teams are aware gaining prescribers in each team would offer a great benefit to patient care, however, the current situation is that all teams are located off the main trust site. This means clinicians and patients have no access to the pharmacy for prescriptions, nor to other prescribers for training and support. This is an area that needs to be looked at in further detail to see how this can be changed in the future to further improve this pathway.

Given this, NICE published the following guidance, available at:

<https://www.nice.org.uk/guidance/ng210> Pelvic floor dysfunction: prevention and non-surgical management [NG210] Published December 2021

NICE states:

Intravaginal devices for urinary incontinence

1.6.21 Consider a trial of intravaginal devices for women with urinary incontinence, only if

other non-surgical options have been unsuccessful.

Why the committee made the recommendations

The evidence on intravaginal devices was unclear, with variance across outcomes. For example, there was no measurable reduction in urinary leakage, but women reported that their symptoms improved. However, the committee noted that a subjective improvement in symptoms was still important, because it is an indication of the woman's perception of the device's success. The committee were also aware from their experience that these devices can help to prevent urinary leakage in certain circumstances (for example, during exercise). 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.

Background

Patients with stress urinary incontinence are assessed in a specialist pelvic health clinic to discuss and advise on conservative management for their symptoms. This management includes tailored and progressive pelvic floor muscle exercises, exercise advice, fluid advice and discussion regarding weight loss where appropriate. If these measures do not improve the patient's symptoms to a satisfactory level the option of surgery would be discussed. If this was deemed not suitable for the patient, they declined, or was not the right time for them then a continence device may be suggested to minimise symptoms to allow the patient to continue usual activities / exercise.

Following the upload of the PAD holding statement in March 2023 this has resulted in some patients being able to afford the product privately and others having no other option but to manage their symptoms aside from proceeding to surgery. It also results in many patients ceasing exercise as they are unable to continue due to it exacerbating their symptoms.

If the use of intravaginal devices for urinary incontinence is accepted, it is planned that these devices may be discussed for patients where their symptoms are leading them to stop exercise and / or, after conservative management and surgery have been trialled / offered. Within physiotherapy the patient would be questioned on when they might use the device and how frequently. From this the physiotherapist would then advise on the most cost-effective continence device. If the patient deemed this option is not suitable an alternative continence device may then be offered.

The APC is asked to support primary care prescribing of the continence devices. The pelvic physio teams would then offer a 1:1 patient review to support with sizing and any queries on use, the patient would remain on open access for 6 months in case any further queries arise.

Assessment

By enabling prescribing by primary care colleagues for these continence devices it would provide patient choice as per NICE guidelines, offering these devices after other conservative measures have failed. The specialist pelvic health clinic encourage and support women to continue to exercise, which in turn has cardiovascular benefits, improved BMI management and aids bone density, which is particularly prevalent in the target population.

There are 4 products on the market (costs below in financial implications are for repeat prescriptions, once patient has been sized).

1. Efemia bladder support
2. Contiform Vaginal Pessary
3. Contrelle Activgard
4. Diveen

Intravaginal devices are designed to help manage urinary incontinence, particularly stress

urinary incontinence (SUI). They work by:

Support Mechanism: These devices are inserted into the vagina to support the bladder neck or compress the urethra, which helps reduce or prevent urine leakage.

Types of Devices:

Pessaries:

These are reusable devices that provide support to the bladder neck. They are often used for both urinary incontinence and pelvic organ prolapse.

Bladder Support Devices: (Discussed in this APC paper)

These are typically single-use, disposable devices that are inserted using an applicator. They expand to provide support to the urethra

These devices are generally used during activities that increase abdominal pressure, such as exercising, coughing, or lifting would be advised on the most cost-effective product depending on their intention for use. For example:

- a patient who is leaking on all walking / activity and may use the product four times a week or more would be directed towards the Efemia that is reusable for as many uses as required for 3 months.
- a patient who wishes to use this for high intensity exercise two – three times a week could use either the Efemia or Contiform.

Patients would need to be assessed for suitability and sized, if necessary; this would occur in the pelvic health physiotherapy clinic. They would also be provided a patient information leaflet to advise on what to look out for, when to stop use and how to seek help. The patients would be offered 6 months open access to the physiotherapy clinic, once set up with this product so they can return for review if there are any concerns or complications. After the 6 months has elapsed the patient would be self-managing but could be referred at any time for review of their stress urinary incontinence if needed.

After specialist assessment by the physiotherapist a letter would be sent to the GP informing of the assessment and recommendation, this would include information on complications and contraindications below, informing that the patient was currently clear of these and had been provided written information on stopping use if any of these develop.

Do not use if:

- Pregnant
- Until 3/12 postnatal
- Have active vaginal infection or vaginal erosions
- Current urinary tract infection / cystitis
- Until 6 months after any pelvic surgery
- Undergoing active treatment for pelvic malignancy
- Severe vaginal prolapse
- Have previously suffered toxic shock syndrome

Complications:

- Vaginal discomfort / dryness - if experience vaginal discomfort with using product stop use and consider water based vaginal lubricant or vaginal oestrogen if peri-menopausal or post-menopausal and then retry- if continues cease use.

Place in therapy in other systems:

South-West London

- Have not been considered for addition to the formulary so currently non-formulary but are being prescribed on FP10 (information taken from openprescribing.net)

Sussex ICB

- Have not been considered for addition to the formulary but are being prescribed on FP10 (information taken from openprescribing.net)

Frimley ICB

- Have not been considered for addition to the formulary so currently non-formulary but are being prescribed on FP10 (information taken from openprescribing.net)

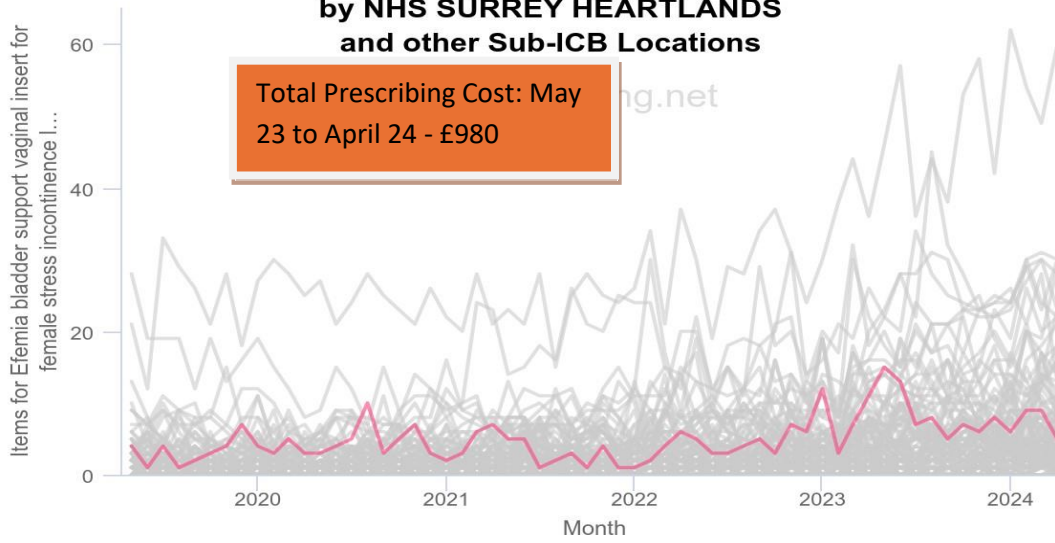
a. Financial assessment - implications/risks

Drug Tariff [accessed 05/08/2024]

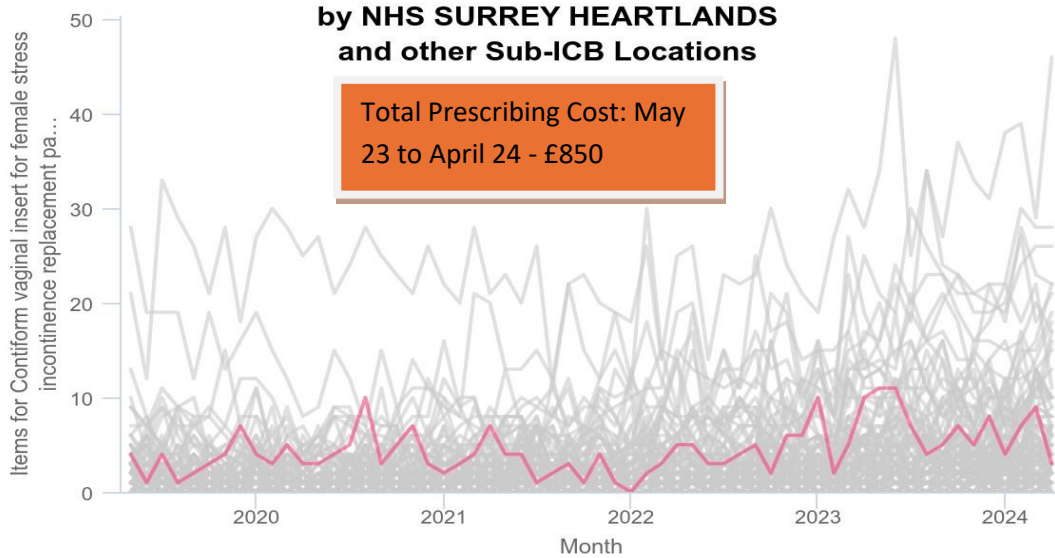
Product	Usage	Starter Pack (sizing kit)	Unit Cost	Yearly cost if worn daily	Yearly cost if used twice a week
Efemia	Reusable for minimum 3/12 but can be up to 1 year	£50.22	£45.09 (single pack of 1 unit)	£180.36 (depending on wear & tear of product)	£45.09 - £180.36 (depending on wear & tear of product)
Contiform	Reusable for at least 30 uses (user checks for wear & tear)	£52.91	£27.33 (single pack 1 unit)	£355.29 for 13 boxes for one year?	£211.64 - as will need up to 4 whole boxes depending on wear & tear)
Diveen	Two uses per unit, 15 units	£8.78	£41.17 (15 devices and applicators)	£535.21 for 13 boxes for one year?	£164.68 for 4 boxes?
Contrelle Activgard	Single use, 30 units	£4.20	£54.38 (30+ uses) (30 devices and applicators)	£706.94	£217.52 as will need 4 whole boxes (potentially less depending on wear & tear)

Prescribing trends over the last few years

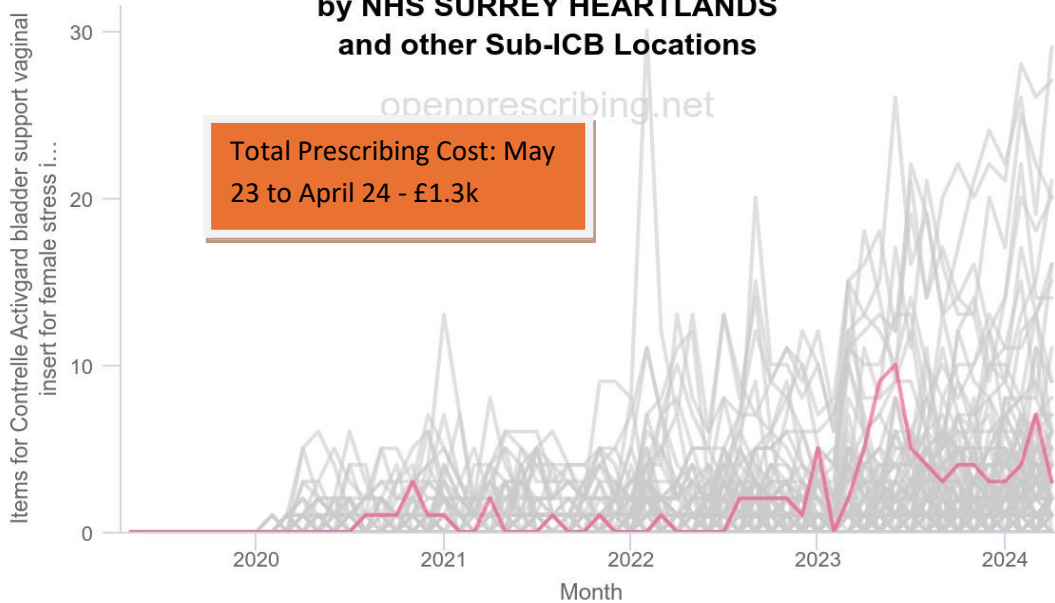
**Items for Efemia bladder support vaginal insert for female stress incontinence I...
by NHS SURREY HEARTLANDS
and other Sub-ICB Locations**



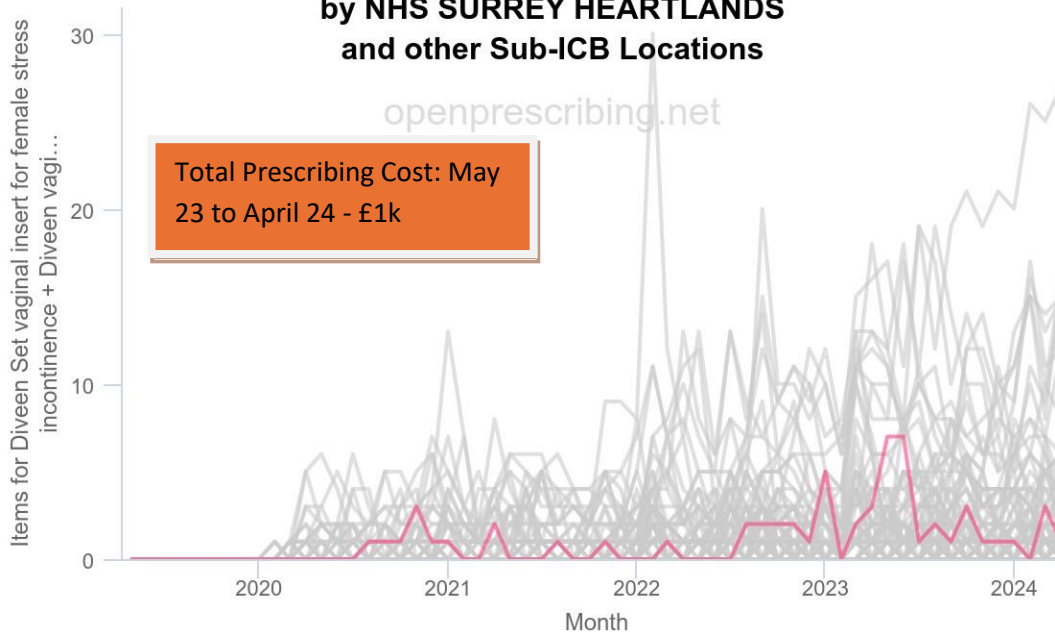
**Items for Contiform vaginal insert for female stress incontinence replacement pa...
by NHS SURREY HEARTLANDS
and other Sub-ICB Locations**



**Items for Contrelle Activgard bladder support vaginal insert for female stress i...
by NHS SURREY HEARTLANDS
and other Sub-ICB Locations**



**Items for Diveen Set vaginal insert for female stress incontinence +
Diveen vagi...
by NHS SURREY HEARTLANDS
and other Sub-ICB Locations**



Summary

Patient information leaflet and template letter to GP attached.

Recommendations

The APC is asked to

- Agree a **BLUE (on recommendation)** traffic light status for a trial and then on-going prescription if needed, of an intravaginal device for women with stress urinary incontinence, only if other non-surgical options have been unsuccessful.
- Agree the letter of recommendation to primary care prescribers
- Agree the PIL leaflet

- Remove the current holding statement from PAD here <https://surreyccg.res-systems.net/PAD/Search/DrugConditionProfile/6655>

BLUE (on recommendation)

Medicine name (generic and brand)	Place in therapy Are you going for this to be based on single use or reusable or for daily or intermittent use?
Efemia bladder support	1 st line choice for daily or intermittent use and 1 st line choice of reusable product
Contiform bladder support	2 nd line choice for daily or intermittent use.
Diveen bladder support	3 rd line choice if other devices not able to be used i.e. due to insertion / comfort etc.
Contrelle Activgard bladder support	This is the only single-use product currently available. This is the most expensive product for daily and intermittent use. Please reserve for those who specifically require this product.

Equality Impact Assessment:

Protected characteristics Protected Characteristics - Information	Describe any considerations or concerns for each group.	Describe suggested mitigations to reduce inequalities.
Age	18+	
Disability		
Gender reassignment	For female anatomy only	
Marriage and civil partnership		
Pregnancy & maternity	Not suitable for use in pregnancy or up to 3 months	

	postnatal	
Race		
Religion and belief		
Sex	For female anatomy only	
Sexual orientation		
Impact on any other vulnerable groups?		

References:

1. <https://www.nice.org.uk/guidance/ng210> Pelvic floor dysfunction: prevention and non-surgical management [NG210] Published December 2021

Declaration of interest:

	Name	Role	Date	Declaration of interests (please give details below)
Prepared by	Jodie Hayward	Clinical Service Lead and Specialist Physiotherapist in Pelvic Health ASPH	05/03/2024	None
Supported by	Clare Johns	Lead Pharmacy Technician (MRU)	17/07/2024	None
Reviewed by	Tejinder Bahra	Lead MRU pharmacist (Operational)	01/08/2024	None

Explanation of declaration of interest:

None.

Version control sheet:

Version	Date	Author	Status	Comment
1	26/07/2024	Jodie Hayward/Clare Johns	Draft	Out for clinical comment (Specialists in other hospitals)
2	09/08/2024	Jodie Hayward/Clare Johns	Final	Out for consultation