

Surrey Heartlands Integrated Care System Area Prescribing Committee (APC)

Integrated Care Partnerships (ICPs) (Surrey Downs, Guildford & Waverley, North West Surrey, East Surrey (as part of the CRESH system) & associated partner organisations.

Formulary Extension Briefing Paper

Medicine details	
Name, brand name	Estradiol Metered-Dose Transdermal Spray (Lenzetto®)
Manufacturer	Gideon Richter (UK) Ltd
Licensed SPC formulation indication	Hormone Replacement Therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women (in women at least 6 months since last menses or surgical menopause, with or without a uterus).
Formulation	1.53 mg/spray, transdermal spray, solution
Usual dosage	is 3 metered-dose sprays (4.59 mg/dato the forearm daily

Disease and potential patient group																	
Brief description of disease	For the management of menopausal symptoms requiring hormone replacement therapy in line with NICE guidance:Menoause ¹ and CKS: Menopause ²																
Potential patient numbers per 100,000	<p>This should provide another option to the current selection and is not expected to immediately increase use. There is an upwards trend in prescribing hormonal treatments for menopause:</p> <table border="1"> <thead> <tr> <th colspan="4">Total prescribing for Sandrena + Lenzetto + Oestrogel across NHS SURREY HEARTLANDS CCG</th> </tr> <tr> <th></th> <th>Jan '22</th> <th>Financial YTD (Apr '21—Jan '22)</th> <th>Last 12 months (Feb '21—Jan '22)</th> </tr> </thead> <tbody> <tr> <td>Cost (£)</td> <td>19,128</td> <td>153,828</td> <td>174,704</td> </tr> <tr> <td>Items</td> <td>1,647</td> <td>14,254</td> <td>16,196</td> </tr> </tbody> </table> <p><i>Openprescribing, accessed March 2022</i></p>	Total prescribing for Sandrena + Lenzetto + Oestrogel across NHS SURREY HEARTLANDS CCG					Jan '22	Financial YTD (Apr '21—Jan '22)	Last 12 months (Feb '21—Jan '22)	Cost (£)	19,128	153,828	174,704	Items	1,647	14,254	16,196
Total prescribing for Sandrena + Lenzetto + Oestrogel across NHS SURREY HEARTLANDS CCG																	
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SUMMARY

Reason for formulary extension	
<p>There is an ongoing review of the Menopause guidelines for Surrey Heartlands, and Lenzetto® is one of the new products being reviewed for the new guidelines as there has been significant interest in it's use, especially from private specialists and direct patient requests.</p> <p>There is a current shortage of transdermal oestrogens for hormone replacement therapy (HRT) and therefore the Area Prescribing Committee is asked to give an interim approval for this product until it can be reviewed in full for the menopause guidelines.</p>	
Tick one box	
Addition to formulary product/s	Y
Replacement of originator product/s.....	
Name of	
Evidence as necessary	
<p><u>Introduction:</u></p> <p>This is an alternative formulation for existing treatments with a well described place in therapy in CKS.</p> <p>The questions that remain in order to approve this product are as follows³:</p>	

- What is the likely dose to be required from the wide dosage window (1-3 sprays)
- What will be the cost implications
- Will this formulation be effective in the 'real world'? Oestrogen gels need to be applied over a large area in order to achieve adequate absorption. The alternative transdermal preparations are patches which remain in continuous contact with the skin. This formulation is applied to a much smaller area than for the gels, and absorption is enhanced by a dermal penetration enhancer, which is a novel route for this treatment.

Discussion:

In order to obtain a license, the manufacturer's needed to demonstrate clinical efficacy. 'Studies suggest that compared to applying it to the inner surface of the forearm, absorption of estradiol is similar when Lenzetto is applied to the skin of the thigh, but is lower when applied to the skin of the abdomen'

Dr. Bahar Maybrey⁵, who has used this product as she also works at Guy's Hospital where this has been approved to the formulary, shared the following experience:

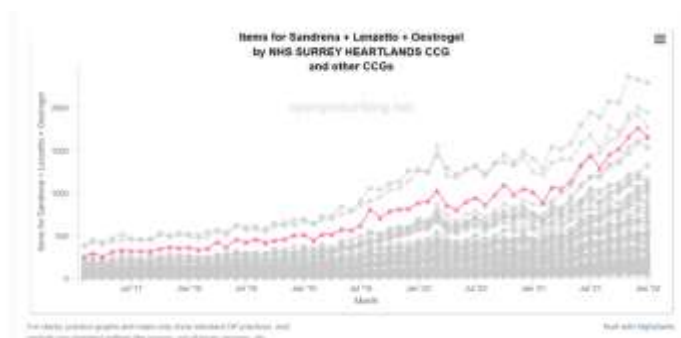
Most patients respond well to 1-2 sprays. It is important to follow the instructions and use on the forearms. Her experience also suggests that it is useful to continue spraying in the same place otherwise absorption appears to have been less. Higher doses are more likely to be required after surgical menopause and in younger people.

Cost implications

Cost of product:

Annual cost per patient: £44.85 to £134.55 per annum (1 to 3 sprays per day)

Costing information/100,000 population and per CCG: In the last 12 months, approximately 16,000 items were dispensed in Surrey Heartlands at a cost of £175,000. It is not likely that this option will increase costs. There is however a trend away from the less expensive oral HRT to transdermal HRT as, unlike the former, the latter do not appear to increase risk of thromboembolism^{1,3}:




Availability of PAS and details (if appropriate): No

Availability of homecare service (if appropriate): No, primary care prescribing which does not incur VAT.

Alternative treatments and cost per (patient per year / per month as appropriate)

	Min Dose	Cost per year	Max Dose	Cost per year
Lenzetto®	1 spray per day	£89.70	3 sprays per day	£134.55
Oestrogel®	2 pumps per day	£55.32	4 pumps per day	£110.64

Sandrena®	1 x 500mg sachet	£10.93	1 x 500mg sachet + 1 x 1mg sachet	£142.09
Impact to patients				
<p>Feedback from some who have prescribed is that some patients really like it as it is very quick to use, and they do not like patches, whereas others do not like the spray action, size of the nozzle, and/ or find actuation difficult.</p> <p>Caution is required after application especially with regards to contact with others or pets, and changes in absorption as a result of sun creams⁸</p>				
Impact to primary care				
<p>There is currently a supply shortage of all transdermal gels, and it is possible that this will also lead to shortages of the transdermal patches, and these shortages have happened periodically over the last few years. This product will provide patients with another option when other products are out of stock, and some patients may prefer this method of administration. It is not expected that this will create additional work and costs beyond the described year-on-year increase in HRT prescribing, and especially for transdermal preparations. This is a new formulation with a novel method of administration, therefore primary care prescribers will need to become familiar with the method of administration and special precautions,</p> <p>After delivery of 56 sprays, the container must be discarded even if there is some leftover solution in it. The number of sprays made should be marked using the table on the carton. As drug residue will remain in the used up containers, they should not be disposed of via household waste. Empty containers should be returned to the pharmacy for destruction.</p>				
Impact to secondary care				
<p>HRT does not require urgent initiation, and, in almost all cases, does not require specialist referral³. Patients admitted to hospital on HRT should not have their treatment stopped suddenly, especially if on transdermal preparations as these are not expected to cause an increase of thrombotic events. HRT formulations are interchangeable in this scenario if secondary care do not have a supply. This application is not, therefore, expected to impact on secondary care.</p>				
Impact to CCGs				
It is not expected to impact CCGs				
Implementation				
<p>An updated menopause pathway is in its' final stages of development as per workplan and will be presented to the Area Prescribing Committee in the near future.</p> <p>Lenzetto® is a transdermal oestrogen hormone replacement treatment that should be prescribed in accordance to CKS-Menopause: Hormone Replacement Therapy (HRT)² in the same place in therapy as Oestrogel® and Sandrena®. The area prescribing committee is being asked to either agree to the introduction of this formulation to the health economy temporarily for the duration of the product shortages, and request further discussion within the new menopause guidelines and formulary, or to agree the introduction of this formulation without the need for further discussion.</p>				
Recommendation to APC				
PbRe: N				
 Colour classification guidelines				
Recommended traffic light status (see attached guidelines):				

GREEN traffic light classification

Additional comments:

Updated Menopause guideline in final stages of development.

References:

1. NICE Guidance, Menopause: diagnosis and management (NG23) Published: 12 November 2015 Last updated: 05 December 2019, <https://www.nice.org.uk/guidance/ng23>
2. CKS:Menopause, accessed March 2022, <https://cks.nice.org.uk/topics/menopause/>
3. Discussion in the Surrey Heartlands Women's Health Medicines Network meeting, January 2022
4. Lenzetto Medicines Evidence Pack, Gideon Richter, received February 2022 (attached)
5. Verbal Communication, Dr. Bahar Maybrey, Oxted Health Centre, GP with a Special interest in Women's Health
6. Openprescribing, accessed March 2022, <https://openprescribing.net/analyse/#org=CCG&orgIds=92A&numIds=0604011G0BP,0604011G0BW,0604011G0BI&denom=nothing&selectedTab=summary>
7. SPC, Lenzetto, accessed March 2022, <https://www.medicines.org.uk/emc/product/11175#PRODUCTINFO>
8. PIL Lenzetto, accessed March 2022, <https://www.medicines.org.uk/emc/product/11175/pil>

Prepared by:

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Declaration of Interest:

None

Date: Thursday, 31 March 2022

Reviewed by:

Name, Designation, Organisation

Declaration of Interest:

XXXX

Date: XXXX

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
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v.1	31/03/22	CJO		Urgent AOB for the APC meeting on the 6 th April 2022, prepared due to severe product shortage of alternatives
v.2				