

**South East London Area Prescribing Committee  
Formulary recommendation**

<b>Reference:</b>	<b>112</b>
<b>Intervention:</b>	<b>Prasterone pessaries (Intrarosa<sup>®</sup>) vulvar and vaginal atrophy in postmenopausal women having moderate to severe symptoms</b> (Prasterone is a precursor steroid which is inactive by itself and it is converted into oestrogens and androgens)
<b>Date of Decision:</b>	<b>October 2019</b>
<b>Date of Issue:</b>	<b>November 2019</b>
<b>Recommendation:</b>	<b>Amber 2 – initiation and first prescription from the specialist gynaecology team</b>
<b>Further Information</b>	<ul style="list-style-type: none"> <li>• Prasterone pessary (Intrarosa<sup>®</sup>) is accepted for use in South East London in line with its licensed indication i.e. for the treatment of vulvar and vaginal atrophy in postmenopausal women having moderate to severe symptoms.</li> <li>• Intrarosa<sup>®</sup> is <b>not</b> a first line option in this setting and should only be initiated for symptoms that adversely affect quality of life. Use of Intrarosa is accepted in line with the following criteria:             <ul style="list-style-type: none"> <li>- Topical lubricants have been adequately trialled and</li> <li>- <b>At least two topical oestrogen preparations</b> have been adequately trialled and these have failed to control symptoms and improve quality of life.</li> </ul> </li> <li>• The initial prescription and supply will come from the initiating specialist team. Prescribing can then be continued in primary care.</li> <li>• Patients will be reviewed by the clinic 3 months after treatment to assess efficacy and adverse effects.</li> <li>• Long term data on the use of Intrarosa<sup>®</sup> are lacking. There should be regular review of patients to ensure ongoing effectiveness and safety. A careful appraisal of the risks and benefits should be reassessed <b>at least every 6 months</b>. Intrarosa<sup>®</sup> should only be continued as long as the benefit outweighs the risk.</li> <li>• There are a number of contraindications to the use of Intrarosa<sup>®</sup>, including known, past or suspected breast cancer, known or suspected oestrogen-dependent malignant tumours (e.g. endometrial cancer) and previous or current venous thromboembolism. Please refer to <a href="#">SPC</a> for the complete list and further detail.</li> <li>• This approval for this recommendation is time limited to <b>1 year</b> to enable experience of use with the preparation. A report summarising outcomes with Intrarosa<sup>®</sup> over this period will be presented back to the Committee after 1 year. <b>This report will be coordinated across all trusts in SEL by the original formulary applicant</b> and will include:             <ul style="list-style-type: none"> <li>- The total number of patients treated with Intrarosa<sup>®</sup> across SEL</li> <li>- Whether use is in line with this recommendation</li> <li>- Impact on patient related outcomes, such as (i) adverse effects (ii) efficacy, including symptom control and quality of life improvements</li> <li>- The number of patients discontinuing treatment and reasons for stopping</li> </ul> </li> <li>• Prasterone is a Schedule 4 (part 2) controlled drug (anabolic steroids).</li> </ul>
<b>Shared Care/ Transfer of care required:</b>	N/A.

<b>Cost Impact for agreed patient group</b>	<ul style="list-style-type: none"> <li>• The original formulary application estimated approximately 150 patients per year in SEL might be treated with prasterone pessaries.</li> <li>• However, when presenting to the Committee, the applicant stated that the numbers are expected to be lower, around 6 patients per year per Trust.</li> <li>• If it is therefore assumed that between 20 -150 patients might be treated with prasterone pessaries, the cost impact across SEL is expected to range between ~£4k to ~£31K per year (excluding VAT).</li> </ul>
<b>Usage Monitoring &amp; Impact Assessment</b>	<p><b>Acute Trusts:</b></p> <ul style="list-style-type: none"> <li>• Monitor and audit use as agreed and report back to the Committee in 12 months (data to be collated and presented no later than <b>January 2021</b>).</li> </ul> <p><b>CCGs:</b></p> <ul style="list-style-type: none"> <li>• Monitor EPACT 2 data and exception reports from GPs if inappropriate prescribing requests are made to primary care.</li> </ul>
<b>Evidence reviewed</b>	<p><b>References (from evidence evaluation)</b></p> <ol style="list-style-type: none"> <li>1. Up to date. Online clinical resource. Accessed online via: <a href="http://www.uptodate.com">www.uptodate.com</a>. Last accessed 18/09/19.</li> <li>2. National Institute for Health and Care Excellence. Menopause: diagnosis and management [NG23]. Published November 2015. Accessed online via: <a href="https://www.nice.org.uk/guidance/ng23">https://www.nice.org.uk/guidance/ng23</a>. Last accessed 18/09/19.</li> <li>3. Prasterone for vulvar and vaginal atrophy. Drug and Therapeutics Bulletin. Published Online First: 02 October 2019. doi: 10.1136/dtb.2019.000034</li> <li>4. Summary of Product Characteristics. Intrarosa 6.5 mg pessary. Last updated March 2019. Accessed online via: <a href="https://www.medicines.org.uk/emc/product/9986/smpc#">https://www.medicines.org.uk/emc/product/9986/smpc#</a>. Last accessed 18/09/19.</li> <li>5. Specialist Pharmacy Service. Prasterone. Published 10th February 2016, updated 18th September 2019. Accessed online via: <a href="https://www.sps.nhs.uk/medicines/prasterone/">https://www.sps.nhs.uk/medicines/prasterone/</a>. Last accessed</li> <li>6. Archer D et al. Treatment of pain at sexual activity (dyspareunia) with intravaginal dehydroepiandrosterone (prasterone) (2015). <i>Menopause</i>; 22(9): pages 950-963.</li> <li>7. Labrie F et al. Efficacy of intravaginal dehydroepiandrosterone (DHEA) on moderate to severe dyspareunia and vaginal dryness, symptoms of vulvovaginal atrophy, and of the genitourinary syndrome of menopause (2016). <i>Menopause</i>; 23(3): pages 243-256.</li> <li>8. Labrie F et al. Effect of intravaginal prasterone on sexual dysfunction in postmenopausal women with vulvovaginal atrophy. <i>International Society for Sexual Medicine</i>; 12: pages 2401-2412.</li> <li>9. Labrie F et al. Prasterone has parallel beneficial effects on the main symptoms of vulvovaginal atrophy: 52-week open-label study (2015). <i>Maturitas</i>; 81: pages 46-56.</li> <li>10. European Medicines Agency. Committee for Medicinal Products for Human Use (CHMP). Assessment report. Intrarosa (Nov 2017).</li> </ol>

**NOTES:**

- a) Area Prescribing Committee recommendations and minutes are available publicly on the [APC website](#).
- b) This Area Prescribing Committee recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.
- c) **Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**