

## **CLINICAL GUIDELINE**

# **Urogenital atrophy management**

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

Version Number:	2	
Does this version include changes to clinical advice:	Yes	
Date Approved:	7 <sup>th</sup> November 2024	
Date of Next Review:	30 <sup>th</sup> November 2029	
Lead Author:	Claire Higgins & Frances Lowrie	
Approval Group:	Gynaecology Clinical Governance Group	

#### **Important Note:**

The Intranet version of this document is the only version that is maintained.

Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

### **Management of Urogenital Atrophy**

### Aim/Objective of the guideline:

To provide information on options for the management of symptoms due to urogenital atrophy

#### Audience:

All healthcare professionals involved in the care of women affected by urogenital atrophy

#### **Guideline:**

Urogenital atrophy describes changes to the tissue quality of the vulva, vagina, urethra and bladder trigone, secondary to reduced tissue estrogen exposure usually associated with the menopause. Symptoms are not necessarily controlled by systemic HRT, and local therapies are commonly needed.

Alternative terminologies include genitourinary syndrome of menopause and vulvovaginal atrophy. However, urogenital atrophy is preferred terminology used by the British Menopause Society (3).

Reported prevalence rates vary, with approximately 1 in 4 women having symptoms prior to menopause, 1 in 2 women after the menopause, and 70% of women affected in their 70s.

The impact of vaginal dryness on relationships, quality of life, daily activities, and sexual function can be significant, but is frequently underestimated. Furthermore, barriers exist to treatment-seeking, with the condition often under reported and undertreated.

#### **Symptoms**

Reported symptoms relate to the organs affected including, vulvovaginal itching, dryness, burning and discomfort. Women will often describe pain with sex or with internal vaginal examinations. Women may also experience vaginal bleeding, discharge and infection. Urinary symptoms include recurrent urinary tract infections, urinary frequency, urgency and dysuria.

## **Examination Findings**

There may be limited findings on examination, despite significant symptoms.

Vulvovaginal dermatoses including lichen sclerosus, lichen planus, dermatitis, vulval intraepitherial neoplasia (VIN) and vulval carcinoma may present with similar symptoms, therefore careful history taking and examination should be considered.

Changes to the vulva can include loss of fat deposition in the labia majora, thinning, fusion or loss of the labia minora. Genital hair growth can be reduced. The urethra may become more prominent and may prolapse leaving women susceptible to ascending infection.

Vaginal changes with change in discharge and infection susceptibility are mediated by reduced number and turnover of superficial mucosal cells. In the well estrogenised vagina, superficial cells turnover every 4 hours, contributing to the release of glycogen to support lactobacilli which in turn maintains the low pH of the vagina. Mucosal thinning will leave the vaginal tissue prone to trauma, and the increase in pH with loss of lactobacilli leave the vagina prone to infection.

Loss of elasticity of the vagina is due to reduced collagen formation as the fibroblasts within the vaginal wall become dormant in response to loss of estrogen. This leads to loss of vaginal rugae, shortening of the vagina and associated prolapse.

#### **Management options**

An overview of treatment pathways is summarized by the British Menopause Society in Appendix 1.

#### Lifestyle modifications

These include smoking cessation (smoking can increase the metabolism of estrogen) and regular sexual activity to increase blood flow to the urogenital organs. Exercise activity should also be encouraged to reduce the prevalence of symptoms.

#### Vulvo-vaginal general measures

General hygiene measures should be addressed, including avoidance of irritants including soap products, bath additives, scented products and sanitary pads.

Alternatives to soap include QV gentle wash©, Aveeno® products, Oil based emollients such as Hydromol®, Cetraben®, Epaderm® ointments.

#### Vaginal estrogen

Locally delivered vaginal estrogen therapy is the current gold standard for management of the symptoms of urogenital atrophy. It acts by enhancing genital blood flow which restores cell maturation, healthy bacterial flora and encourages a vaginal pH <5. Vaginal secretions and peripheral nerve function are also improved.

Effects may not be apparent until a number of months of treatment are complete. Monitoring on endometrial thickness is not required with vaginal estrogen therapy when used as outlined below.

Treatment choices include natural estrogens, such as estradiol (E2) delivered as a small vaginal tablet or ring or the weaker estrogen, estriol (E3) delivered as a cream (either 0.1% or 0.01%), a waxy pessary or an oily gel. First line treatment will be determined by patient preference.

Table 1 Summary of vaginal estrogen products

Product name Active Estragen		Mothod of uso	
Product name	Active Estrogen	Method of use	
Vagifem®,	Estradiol	Insert 1 pessary vaginally every night for 2	
Vagirux <sup>®</sup> , Gina <sup>®</sup>	(10mcg/pessary)	weeks, then 1 pessary twice a week	
Ovestin®	Estriol	Insert 1 applicator volume every night for 3-4	
Estriol cream	(500mcg/applicator)	weeks, then twice a week	
0.1%			
Gynest®	Estriol	Insert 1 applicator volume every night for 3-4	
Estriol cream	(500mcg/applicator)	weeks, then twice a week	
0.01%		*arachais oil ingredient, avoid in peanut allergy	
Imvaggis® oily	Estriol	Insert 1 pessary every night for 3 weeks, then	
pessary	(30mcg/pessary)	twice a week	
Blissel® Gel	Estriol (50mcg/applicator)	Insert 1 applicator volume every night for 3-4 weeks, then twice a week	
Estring <sup>®</sup>	Estradiol (7.5mcg daily release)	Insert 1 vaginal ring into the vagina, change after 3 months	

#### Vaginal Estrogen in breast cancer patients

There is low systemic absorption, particularly with prolonged use encouraging maturation of the vaginal wall. Recent evidence suggest no increase in breast cancer associated mortality in breast cancer survivors who used vaginal estrogen therapy (4).

In women using Tamoxifen, it is suggested that in discussion with their breast care team, that vaginal estrogen can be safely used as it does not appear to cause a significant increase in breast cancer recurrence or survival (5). However, the same study suggested increase risk of recurrence if vaginal estrogen used where women are taking aromatase inhibitors, and thus alternative non-hormonal therapies should be used in these women (5).

#### Non-hormonal lubricants and moisturisers

Vaginal lubricants and moisturisers can be used alone or in conjunction with vaginal estrogen therapies. Additionally, application of lubricants can be used to facilitate sexual

intercourse or the use of vaginal dilators. Care should be taken as oil based products cause damage to latex condoms.

Lubricants and moisturisers are **first line** recommended treatment for women in whom estrogen is contraindicated.

Lubricants act quickly to reduce friction when applied to the vulva/vagina and partners penis/ vaginal dilator prior to insertion. Some products can be used in combination, with one partner using a water based product and the other using an oil based product e.g. 'Double Glide' effect combining Yes®WB and Yes®OB.

Moisturisers act to mimic natural vaginal secretions, rehydrate vaginal mucosal tissue, adhere to the vaginal lining and will lower vaginal pH. Moisturisers are used 2-4 times a weeks.

When choosing products, it is important to consider osmolality and pH. Hyperosmolality can cause cellular damage and markedly reduce vaginal epithelial cells. The osmolality of vaginal secretions is 260–290 mOsm/kg, and products in this range may be preferable. However, many commercially available products are much higher than this. WHO recommend that osmolality should be less than 1200 mOsm/kg, aiming to be as near to physiological levels as possible (6).

The aim for pH is to within physiological range. For products intended for vaginal use, a pH around 4.5 is recommended.

Many products are available to purchase over the counter, with some available on prescription from primary care. A summary of the products compatible with recommended pH and osmolality for vaginal use is provided below.

	Available on NHS prescription (Part 3 of Drug Tariff, Scotland (9))	Compatible with latex condoms
Sylk® Natural Lubricant	Yes	Yes
Yes® WB (Water-Based personal Lubricant	Yes	Yes
Yes® VM (pH matched vaginal moisturiser)	Yes	Yes
Yes® OB (Oil-Based Lubricant)	No	No
Balance Activ <sup>®</sup> Moisture Gel	No	No
Good Clean Love® Restore moisturizing vaginal gel	No	Yes
System Jo® Personal Lubricant	No	Yes
Durex Sensilube® Hydrating Intimate Gel Lubricant	No	Yes

**Table 1** Suggested vaginal moisturisers and lubricants which are within the recommended pH and osmolality ranges for vaginal use.

## Specialist pelvic floor physiotherapy

This can be considered as an adjunct to help pelvic floor pain and facilitate penetrative sex.

## • Ospemifene, Senshio® 60mg once daily oral tablet

Ospemifene is a selective estrogen receptor modulator (SERM). The Scottish Medicines Consortium indication for use is for the treatment of moderate to severe symptomatic urogenital atrophy in post-menopausal women who are not candidates for local vaginal oestrogen therapy.

It displays estrogen-like effects within the vagina, increasing the cellular maturation and mucus production in the vaginal epithelium.

There is an antagonist effect on the endometrium and breast tissue. It is suggested it can be used in women with a history of breast and endometrial cancer, who have completed treatment. However, it should not be used where treatment is still in progress or in those with endometrial hyperplasia. Additionally it should not be use in women with a current or past history of VTE (8).

Initiation of therapy in secondary care only.

## Dehydroepiandrosterone (DHEA), Prasterone®, 6.5 mg a pessary (once daily dosing)

When DHEA is delivered vaginally, it is converted into estrogens and androgens by enzymes within the epithelial cells of the vagina. It can be used in conjunction with systemic HRT.

There is insufficient safety information for use in women with hormone dependent cancers (including breast and gynaecological), therefore it is not currently recommended in this group of women.

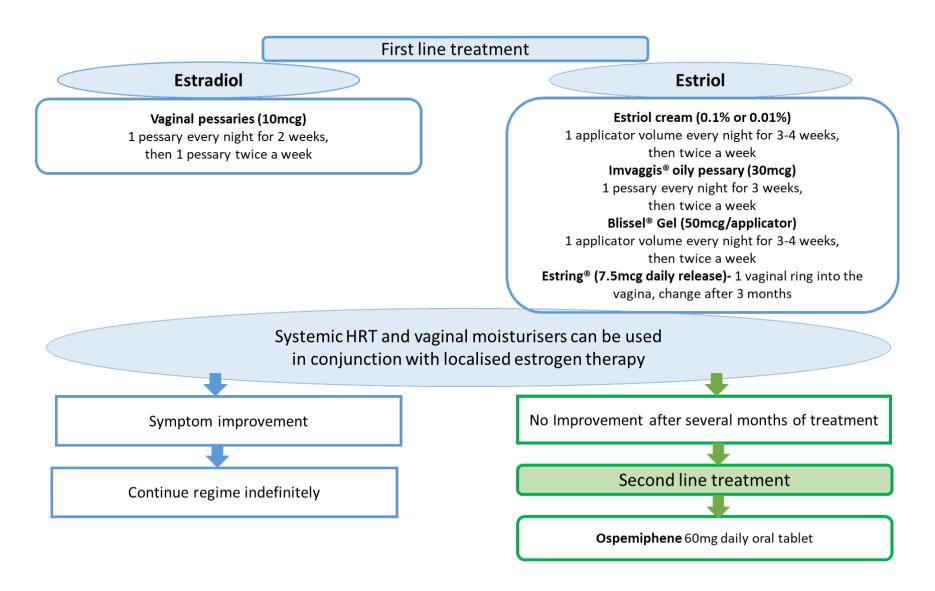
\*\*Of note Prasterone (DHEA) is not currently approved by Scottish Medicines
Consortium for use in NHS Scotland\*\*

## Laser therapy

Women may be aware that external providers can offer laser therapy as a non-hormonal alternative to treatment of urogenital atrophy. These can include CO2 micro ablative laser (The MonaLisa Touch®) and Erbium Yag non-ablative photothermal laser therapy, (Juliet®).

However, current NICE recommendations suggest that long-term safety and efficacy is inadequate and therefore this procedure should only be used in the context of research (2).

**Appendix 1** Suggested treatment pathway for urogenital atrophy in GG&C in women with no contraindication to Estrogen (adapted from BMS consensus statement, Urogenital Atrophy, March 2024)



#### References:

- Menopause: diagnosis and management. NICE guideline [NG23]Published: 12 November 2015 Last updated: 05 December 2019
- 2. Transvaginal laser therapy for urogenital atrophy, Interventional procedures guidance [IPG697]Published: 26 May 2021, NICE
- 3. BMS consensus statement, Urogenital Atrophy, March 2024 <a href="https://thebms.org.uk/wp-content/uploads/2024/04/09-BMS-consensusStatement-Urogenital-atrophy-MARCH2024-A.pdf">https://thebms.org.uk/wp-content/uploads/2024/04/09-BMS-consensusStatement-Urogenital-atrophy-MARCH2024-A.pdf</a>
- 4. McVicker L, Labeit AM, Coupland CAC, et al. Vaginal Estrogen Therapy Use and Survival in Females With Breast Cancer. JAMA Oncol. 2024;10(1):103–108. doi:10.1001/jamaoncol.2023.4508
- 5. Cold S, Cold F, Jensen M-B, Cronin-Fenton D, Christiansen P, Ejlertsen B. Systemic or vaginal hormone therapy after early breast cancer: a Danish observational cohort study. J Natl Cancer Inst. 2022;114(10):1347-1354.
- Use and procurement of additional lubricants for male and female condoms: WHO/UNFPA/FHI360 Advisory note, 2012 WHO RHR 12.33 eng.pdf;sequence=1.pdf
- Edwards, D., & Panay, N. (2015). Treating vulvovaginal atrophy/genitourinary syndrome of menopause: how important is vaginal lubricant and moisturizer composition? Climacteric, 19(2), 151– 161. https://doi.org/10.3109/13697137.2015.1124259
- 8. ospemifene (Senshio) (scottishmedicines.org.uk)
- 9. 2024-09-sdt-part-3.pdf (publichealthscotland.scot)

Authors: Dr Claire Higgins Consultant O&G QEUH; Frances Lowrie W&C Pharmacist QEUH Authorised by: Dr Vanessa Mackay, Clinical Director, Gynaecology Last reviewed: November 2024

Date of next review: November 2029