

**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.

Application for medicines described in CKS, NICE guidance and/or other national guidance

Name of guidance	CKS: Hormone replacement therapy (HRT) Update February 2025 This CKS topic is largely based on the National Institute for Health and Care Excellence (NICE) clinical guideline Menopause [NICE, 2019] and various British Menopause Society (BMS) publications.
Available at	https://cks.nice.org.uk/topics/menopause/prescribing-information/hormone-replacement-therapy-hrt/

The APC will have 4 options when asked to consider the application/s:

1. To accept
2. To reject
3. To allocate alternative traffic light classification
4. To request a full evidence review.

The traffic light status for the Surrey PAD is available at:



FINAL April 2023
Colour classification g

Safety Notice:

Unopposed estrogen replacement is associated with a significant increase in the risk of endometrial hyperplasia that is both dose and duration dependent with exposure between one and three years. Non-hysterectomised women require progestogen administered for 12–14 days in a sequential regimen and daily in a continuous combined regimen to minimise the risk of endometrial hyperplasia and endometrial cancer associated with unopposed estrogen exposure. Healthcare Professionals should be aware of [BMS guidance](#) when prescribing HRT.

The Surrey Heartlands Area Prescribing Committee does not support prescribing of HRT with oestrogen doses above those specified in the license. This is because there is insufficient evidence of efficacy or safety to support this. Specialists may prescribe higher doses of oestrogens with the appropriate opposing progestogen doses but need to retain prescribing responsibility and not transfer prescribing to primary care..

Where specialists take the responsibility of initiating higher doses of oestrogens, they should do so for a limited period of time and retain prescribing responsibility for both oestrogens and associated progestogens. They should be aware of the BMS guidance with regards to requiring increased doses of progestogens to ensure adequate endometrial protection

Medicine name (generic and brand)	Place in therapy	Recommended traffic light	Comments Must include <ul style="list-style-type: none"> • cost impact and by how much. • impact on workload, e.g. monitoring.
Sequential combined therapy			
Femoston® Tablets Estradiol (1mg, 2mg), Dydrogesterone (10mg)	1 st line for women requiring sequential combined therapy	Green 1st line (Change: previously Green not 1st line)	Although more expensive than the previous 1 st line HRT, Elleste Duet®, it is considered the HRT with the lowest oral risk profile.
Evorel Sequi® Patches Estradiol (50mcg), Norethisterone (170mcg)	Patches preferred option in women with risk factors for Venous Thromboembolism (VTE), or migraine, otherwise consider oral first line	Green 2nd line (Change: previously Green 1st line)	Much more expensive than oral preparations, place in therapy described
Elleste Duet® Tablets Estradiol (1mg, 2mg), Norethisterone (1mg)	2 nd line for women requiring sequential combined therapy, with poor cycle control on Femoston	Green 2nd line (Change: previously Green 1st line)	Least expensive, but not considered as safe as Femoston®

Novofem® Tablets Estradiol (1mg, 2mg), Norethisterone (1mg)	Same formulation as Elleste Duet, not required in the formulary, so propose 'Restricted in case there are product shortages with Elleste- Duet '	Green restricted (Change: previously Green)	No place in therapy unless product shortages
Tridestra® Tablets Estradiol (2mg), Medroxyprogesterone (20mg)	Newer options available	Non-Formulary (Change: previously Green)	Consider changing to newer options (32 items dispensed in last 12 months (Apr'23 – Mar'24)
Trisequens® Tablets Estradiol (2mg, 2mg, 1mg) Norethisterone (1mg)	Newer options available	Non-Formulary (Change: previously Green)	Consider changing to newer options (62 items dispensed in last 12 months (Apr'23 – Mar'24)

Continuous combined therapy

Bijuve® Tablets Estradiol (1mg), Progesterone, (100mg) Capsules	1st line for women requiring continuous combined therapy	Green 1st line (NEW: previously not considered)	1st line for women requiring continuous combined therapy it is considered the HRT with the lowest oral risk profile
Femoston Conti® Tablets Estradiol (500mcg, 1mg), Dydrogesterone (2.5mg, 5mg)	1st line for women requiring continuous combined therapy	Green 1st line (Change, previously Green)	1st line for women requiring continuous combined therapy it is considered the HRT with the lowest oral risk profile
Elleste Duet Conti® Tablets Estradiol (2mg), Norethisterone (1mg)	2 nd line for women requiring continuous combined therapy, with poor cycle control on Femoston Conti®	Green 2nd line (Change: previously Green 1 st line)	Least expensive, but not considered as safe as Femoston Conti®
Evorel Conti® Patches Estradiol (50mcg), Norethisterone (170mcg)	Patches preferred option in women with risk factors for Venous Thromboembolism (VTE), or migraine, otherwise consider oral first line	Green 2nd line (Change: previously Green 1 st line)	Much more expensive than oral preparations, place in therapy described
Femseven Conti® Patches Estradiol (50mcg) Levonorgestrel (7mcg)	Less preferred patch, No place in therapy unless product shortages	Green Restricted (Change: Previously Green)	Evorel Conti® is less expensive

Indivina® Tablets Estradiol (1mg, 2mg), Medroxyprogesterone (2.5mg,5mg)	Newer options available	Non-Formulary (Change: previously Green)	Consider changing to newer options (230 items dispensed in last 12 months (Apr'23 – Mar'24))
Kliofem® Tablets Estradiol (2mg), Norethisterone (1mg)	2 nd line for women requiring continuous combined therapy, with poor cycle control on Femoston Conti®	Green 2nd line (Change: previously Green 1st line)	Least expensive, but not considered as safe as Femoston Conti®
Kliovance® Estradiol (1mg), Norethisterone (500mcg)	2 nd line for women requiring continuous combined therapy, with poor cycle control on Femoston Conti®	Green 2nd line (Change: previously Green 1st line)	Least expensive, but not considered as safe as Femoston Conti®
Premique Low Dose® Tablets Conj. oestr (300mcg) Medroxyprogesterone (1.5mg)	Should no longer be prescribed, recommend switching existing patients	Non-Formulary (Change: previously Green)	Recommend swapping to more modern, lower risk formulation (529 items dispensed in last 12 months (Apr'23 – Mar'24))
Gonadomimetic			
Livial® Tablets Tibolone (2.5mg)	Prescribe generically, switch existing patients	Non-Formulary (No change)	Switch to generic (160 items dispensed in last 12 months (Apr'23 – Mar'24))
Tibolone Tablets (2.5mg)		Green (no change)	
Selective oestrogen receptor modulator			
Senshio® Tablets Ospemifene (60mg)	For initiation on specialist advice only for severe dryness where other treatments are not effective or contra-indicated	NEW: Blue on advice from specialist	Much more expensive than other treatments – listed in CKS
Unopposed oestrogen (if uterus is intact an adjunctive progestogen must be used) <i>(Author's note: This MIMS title is incorrect this should read any remaining uterus rather than intact uterus shall we change?)</i>			
Elleste Solo® Tablets Estradiol (1mg, 2mg)	Preferred tablet	Green 1st Line	

Estraderm MX® Patches Estradiol (25mcg, 50mcg, 75mcg, 100mcg)		Green	Currently no preferences between the patches selected until product shortages resolve
Estradot® Patches Estradiol (25mcg, 37.5mcg, 50mcg, 75mcg, 100mcg)		Green	Currently no preferences between the patches selected until product shortages resolve
Evorel® Patches Estradiol (25mcg, 50mcg, 75mcg, 100mcg)		Green	Currently no preferences between the patches selected until product shortages resolve
FemSeven® Patches Estradiol (50mcg, 75mcg, 100mcg)		Green	Currently no preferences between the patches selected until product shortages resolve
Lenzetto® Spray Estradiol (1.53mg per actuation)		Green	Caution with higher than licensed doses used. Propose max 20 containers per year
Oestrogel® Gel Estradiol (0.06%)	Preferred Gel	Green	
Premarin® Tablets Conj. oestr (300mcg, 625mcg, 1.25mg)	Recommend swapping to more modern, lower risk formulation	Non-Formulary	Recommend swapping to more modern, lower risk formulation
Progynova® Tablets Estradiol (1mg, 2mg)	More expensive than Elleste Solo, only to be prescribed in case of product shortages	Green not 1st line	
Progynova TS® Patches Estradiol (50mcg,100mcg)	Second line to tablets	Green	Currently not preferences between the patches selected until product shortages resolve
Sandrena® Gel Estradiol (500mcg, 1mg)		Green	
Zumenon Tablets Estradiol (1mg, 2mg)	More expensive than Elleste Solo, only to be prescribed in case of product shortages	Green not 1st line	

Adjunctive progestogen

Progesterone Capsules 100mg	1 st line	Green (No change)	
Gepretix® Capsules Progesterone Capsules 100mg	Prescribe generically	Non-Formulary (No change)	
Utrogestan® Capsules Progesterone Capsules 100mg	Prescribe generically	Non-Formulary (No change)	
Medroxyprogesterone acetate Tablets 10mg	For endometrial protection in women who have abnormal bleeding on other HRT	Green second line (More defined place in therapy)	Not in Mims table
Slynd® Drospirenone 4mg tablets	For HRT Unlicensed indication	Non-Formulary	Not approved until more evidence is available and presented to the APC for consideration

Oestrogen only (Vaginal)

Blissel® Vaginal gel Estriol (50mcg)	Restricted: for women who require topical oestrogen HRT, but who do not tolerate oestrogen pessaries or creams.	Green Restricted	399 prescriptions in Surrey Heartlands (Nov'23 – Oct'24) If place in therapy is adhered to, this should not represent a significant increase.
Estring® Vaginal ring Estradiol (7.5mcg)		Green (No change)	
Estriol Vaginal cream (0.01%)		Non-Formulary (No change)	
Estriol Vaginal cream (0.1%)		Green (No change)	
Estriol Vaginal tabs (500mcg)	Note 500mcg dose vs Imvaggis brand 30 mcg	Non-Formulary	Working group did not see a place in therapy for this, could create errors
Gina ®(available OTC) Vaginal tabs Estradiol (10mcg)		Non-Formulary (New for this brand)	Prescribe generically, brand to be purchased OTC
Imvaggis ® Pessary Estriol (30mcg)	No place in therapy identified	Non-Formulary	
Vagifem® Vaginal tabs Estradiol (10mcg)	Prescribe generically	Non-Formulary	
Vagirux® Vaginal tabs Estradiol (10mcg)	Prescribe generically	Non-Formulary	
Estradiol Vaginal Tablets (10mcg)		Green	
Intrarosa® Pessary Prasterone (6.5mg)	For initiation on specialist advice only for severe dryness where other treatments are not effective or contra-indicated	NEW: Blue on advice from specialist	Much more expensive than other treatments – listed in CKS

References:

1. NICE CKS, Menopause, <https://cks.nice.org.uk/topics/menopause/prescribing-information/hormone-replacement-therapy-hrt/>
2. MIMs table for HRT preparations
3. Drug Tariff, accessed online June 2024
4. BNF, accessed on-line June 2024
5. Openprescribing, accessed online June 2024,
<https://openprescribing.net/analyse/#org=CCG&orgIds=92A&numIds=6.4.1.1&denom=nothing&selectedTab=summary>