

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) Last revised in September 2022 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:



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Colour classification g

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 1 st 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 1 st 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 1 st 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 1st 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 1st 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 sprays 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	Requested by specialists for a very specific group of patients - to follow	This drug has not been assessed for formulary status	Unlicensed indication – licensed for contraception

Oestrogen only (Vaginal)

Blissel® Vaginal gel Estriol (50mcg)	Does this have a place in therapy	Non-Formulary	
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)	We do not know if this is still available, Company contacted and no response received	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

Equality Impact Assessment

<p>Protected characteristics Protected Characteristics - Information</p>	<p>Describe any considerations or concerns for each group.</p>	<p>Describe suggested mitigations to reduce inequalities.</p>
Age		
Disability		
Gender reassignment	<p>These guidelines may not meet the requirements for people who have undergone gender reassignment</p>	<p>National recommendations are required.</p>
Marriage and civil partnership		
Pregnancy & maternity		
Race		
Religion and belief		
Sex		
Sexual orientation		
Impact on any other vulnerable groups?		

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>

Declaration of interest:

	Name	Role	Date	Declaration of interests (please give details below)
Prepared by	Carina Joanes	Medicines Resource Unit (MRU) Lead Pharmacist	June 2024	
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