Hertfordshire and West Essex Integrated Care System

NHS Hertfordshire and West Essex Integrated Care Board

Hertfordshire and West Essex Hormone Replacement Therapy Guidance

Introduction

These guidelines and frequently asked questions are intended to help support primary care prescribing in relation to menopause. The recommendations are based on the best available evidence at the time of publication, are intended as advisory and do not replace clinical judgement which should be made on a case-by-case basis. They should be read in conjunction with national guidelines (such as NICE and BMS guidance), and marketing authorisation (SPC) for further prescribing information.

This document provides guidance and answers to frequently asked questions to support clinicians treating women and people registered female at birth with menopause associated symptoms, aged 40 years and over.

The guideline does not cover people who are currently having gender affirming hormone therapy. For those younger than 40 years, see the recommendations in the NICE guideline, **Menopause: identification and management (NG23)** (1) diagnosing and managing premature ovarian insufficiency, including what to discuss with the person. Consider referring people with premature ovarian insufficiency to healthcare professionals with the relevant experience to help them manage all aspects of physical and psychosocial health related to their condition (1).

The guidance has been produced utilising published guidance and in collaboration with the Herts and West Essex Gynaecology working group, including Clinical leads, Pharmacists and GPs with special interest in gynaecology. This pathway has been reviewed and approved for submission by Dr Mark Lim, Associate Medical Director and Consultant in Public Health, Strategy, Planning and Evaluation Directorate for Central East ICB and Sehrish Haidri, Project Manager HWE ICB.

Key

BMS = British Menopause Society
BNF= British National Formulary
CVD = Cardiovascular disease
FSRH – Faculty Sexual and Reproductive Healthcare
HRT = Hormone Replacement Therapy
HWE = Hertfordshire and West Essex
ICB = Integrated Care Board
LNG IUS = Levonorgestrel Intrauterine System
NET = Norethisterone
NICE = National institute of Clinical Excellence
MP = Micronised Progesterone
MPA = Medroxyprogesterone Acetate
OTC = Over the Counter
PPC=Prescription Pre-payment Certificate
SPC=Summary of Products Characteristics
STI = Sexually Transmitted Infections
UTI = Urinary tract infection
VTE = Venous Thromboembolism

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HERTFORDSHIRE AND WEST ESSEX ICB PRIMARY CARE HRT PRESCRIBING GUIDANCE - SUMMARY

This document applies to women and people registered female at birth with menopause associated symptoms, aged 40 years and over and does not cover people who are currently having gender affirming hormone therapy. This document is intended as advisory and does not replace clinical judgement.

ORAL TREATMENT OPTIONS

WITHOUT UTERUS*

Oestrogen Only (no uterus)

- Oestrogen Tablets (Daily)

WITH UTERUS

Sequential Combined (Uterus – monthly bleed)
Still having periods or within 12mths of last period

- **Sequential Combined Tablets** (Oestrogen + Progesterone)
- **Oestrogen Tablets** AND **Progesterone** (sequential oral or LNG IUS)

Continuous Combined (Uterus – no bleed)
Not having periods and more than 12mths since last period

- **Continuous Combined Tablets** (Oestrogen + Progesterone)
- **Oestrogen Tablets** AND **Progesterone** (continuous oral or LNG IUS)

The transdermal route should be considered as first choice route of estradiol administration in menopausal people with risk factors, including those with a BMI >30 kg/m2. (1)

Lower oestrogen Options

Menopausal people ≥60yrs plus should be offered transdermal preparations first line and may require less oestrogen[2] . See later section 'Lack of efficacy, side effects'.

Address modifiable lifestyle factors

- Advise a healthy balanced diet, to maintain a healthy BMI, ensure sufficient dietary calcium and undertake regular weight-bearing exercise.
- Ensure a discussion occurs with the patient in order to address stopping smoking, reducing alcohol intake.
- Ensure optimum treatment of conditions such as diabetes and blood pressure as applicable.

Urogenital Atrophy

Vaginal oestrogen treats vaginal atrophy and can also prevent recurrent UTI type symptoms in postmenopausal people (link). NICE guideline states Offer vaginal oestrogen to people with urogenital atrophy (including those on systemic HRT) and continue treatment for as long as needed to relieve symptoms (1).

Non-hormonal vaginal moisturisers/lubricants (e.g. Replens MD®, Yes VM®) can be used alone or in addition to vaginal oestrogen. **These are available to purchase OTC which may be cheaper than the cost of a prescription charge (not covered by HRT PPC)**

TRANSDERMAL OPTIONS

WITHOUT UTERUS*

Oestrogen Only (No uterus)

- **Oestrogen Patches**
- **Oestrogen Gels (pump, sachet) or Spray**

WITH UTERUS

Sequential Combined (Uterus – monthly bleed)
Still having periods or within 12mths of last period

- **Sequential Combined Patches** (oestrogen & progesterone)
- **Oestrogen Only (Patches, Gel, Spray)** AND **Progesterone** (**sequential** oral or LNG IUS)

Continuous Combined (Uterus – no bleed)
Not having periods and more than 12mths since last period

- **Continuous Combined Patches** (oestrogen & progesterone)
- **Oestrogen Only (Patches, Gel, Spray)** AND **Progesterone** (**continuous** oral or LNG IUS)

***For women and people registered female at birth without a uterus, refer to the section on surgical menopause as those who have had subtotal hysterectomy or hysterectomy for endometriosis may require progesterone.**

Choices of HRT – with associated costs

If a Serious Supply Protocol (SSP) has been issued, pharmacies will supply accordingly against it. Otherwise where products are not available, please consider an alternative clinically appropriate, cost-effective available product (costs available in current online version of BNF and liaise with your local pharmacy) until resolved.

	OESTROGEN ONLY *If uterus present, then use with progestogen as per guidance*	SEQUENTIAL COMBINED HRT *Uterus present - bleed regime Still having periods or within 12mths of last period*	CONTINUOUS COMBINED HRT *Uterus present – no bleed regimen. Not having periods and more than 12mths since last period*
		Oestrogen option plus adjunctive progesterone	
ORAL	**Elleste Solo® Oral Tablets** Estradiol | Drugs | BNF | NICE	**Elleste Duet® Oral Tablets** Estradiol /norethisterone Estradiol with norethisterone | Drugs | BNF | NICE	**Kilovance/Kliofem Tablets** Estradiol / norethisterone Estradiol with norethisterone | Drugs | BNF | NICE
		Femoston® Oral Tablets Estradiol / Dydrogesterone Estradiol with dydrogesterone | Drugs | BNF | NICE	
TRANSDERMAL	**Evorel® Patches** **Estraderm MX® patches** Estradiol | Drugs | BNF | NICE	**Evorel Sequi® Patches** Estradiol / norethisterone Estradiol with norethisterone | Drugs | BNF | NICE	**Evorel Conti® Patches** Estradiol / norethisterone Estradiol with norethisterone | Drugs | BNF | NICE
	Oestrogel® (0.06%) Transdermal Gel Estradiol | Drugs | BNF | NICE		**FemSeven Conti®Patches (ONCE weekly)** Estradiol / levonorgestrel Estradiol with levonorgestrel | Drugs | BNF | NICE
	Sandrena Transdermal Gel Estradiol | Drugs | BNF | NICE		
	Lenzetto Transdermal Spray 1.53 mg/spray Estradiol | Drugs | BNF | NICE		

KEY
Cost per month on average dose
- ≤£5
- ≥£5-£10
- ≥£10

ADJUNCTIVE PROGESTERONE *Use with oral or transdermal oestrogen if uterus present for endometrial protection.*			
Micronised Progesterone Oral Capsules (prescribe generically) *Caution: hypersensitivity to the active substances, soybean lecithin, peanut* Progesterone | Drugs | BNF | NICE	**Levonorgestrel Intrauterine system LNG – IUS (Mirena)** *FSRH supports five years within HRT regimens (NB: Unlicensed after 4 years)* Estradiol with norethisterone | Drugs | BNF | NICE	**Medroxyprogesterone acetate Tablets** Medicinal forms | Medroxyprogesterone acetate | Drugs | BNF | NICE	**Norethisterone Tablets** 15-BMS-TfC-HRT-preparations-and-equivalent-alternatives-JAN2024-B.pdf

VAGINAL ATROPHY	
Estriol 0.1% Intravaginal Cream (0.5g estriol per application) Estriol | Drugs | BNF | NICE	**Estradiol 10mcg Intravaginal Pessary (vaginal tablets) prescribe generically** Estradiol | Drugs | BNF | NICE

TREATMENT COSTS EXAMPLES /Per Month
Combined oestrogen and progesterone tablets
Oestrogen only patch plus micronised progesterone
Oestrogen only patch plus Mirena
Combined oestrogen and progesterone patch
Oestrogen gel plus micronised progesterone
Oestrogen gel plus Mirena

Cost effective prescribing

Decisions on formulation of HRT should be individualised and clinically focused, taking age and other risk factors into account. However to ensure good use of NHS resources, the system also supports cost effective prescribing. Prescribe generically where appropriate, e.g. micronised progesterone and estradiol 10mcg Intravaginal Pessary (vaginal tablets), unless there is justified rationale which should be documented in the notes.

Combined oestrogen and progesterone oral tablets are the cheapest combined formulation available, whilst the most expensive formulations include combined oestrogen and progesterone patches, transdermal gel and sprays plus oral progesterone or Mirena IUS.

FREQUENTLY ASKED QUESTIONS

Transdermal Oestrogen (when this should be first line)

Transdermal Estradiol (patches, gel, spray) should be offered first line in higher risk individuals.

This route avoids the first pass metabolism through the liver, reducing CVD and VTE risks compared to oral Estradiol.

Progesterone is required for women and people registered female at birth with a uterus as per the flow chart above

Transdermal Estradiol dosage, particularly when in the form of an **oestrogen gel or spray**, can also be more easily titrated than oral Estradiol to get the balance right between symptom control and side effects by changing the amount of gel applied.

However, oral HRT can be prescribed in the absence of contraindications, where this is the preferred route after discussion about the risks and benefits.

Transdermal Estradiol is particularly indicated for people with:

- Venous Thromboembolism (VTE) risk factors (includes raised BMI >30kg/m, age >60 years)
- Family history of VTE
- Poor symptom control with oral oestrogen,
- Oestrogenic side effects on oral oestrogen (nausea, headaches etc.)
- Migraine (simple or complicated)
- Variable blood pressure control, diabetes, or other CVD risk factors.
- Current use of liver enzyme inducing medication
- Gall bladder disease
- Malabsorption
- Reduced sex drive since starting oral HRT (other causes excluded)
- Incretin based therapies for weight loss and diabetes

NICE Suggests consider referring people at high risk of VTE (eg strong family history or hereditary thrombophilia) to a haematologist for assessment before considering HRT (1)

When to choose sequential or combined HRT

When to choose sequential or continuous when starting HRT?

- If perimenopausal (still having periods) or within 12 months of last period, start **sequential combined regime**, otherwise start **continuous combined**.
- Sequential combined regime means progesterone for 12 days of each cycle, although the Mirena IUS is an acceptable progestogenic arm.

When to move from sequential to continuous after starting sequential?

- Moving from sequential combined to continuous combined can reduce endometrial risk. (2)
- If over 50 years age, try and move to continuous after 1-2 years.
- If under 50 years, when to switch will involve some clinical judgement. Try to switch to continuous after 18 months, particularly if the periods were relatively infrequent when starting HRT, as this will lower endometrial risk. The switch to continuous should occur by five years of use or by age 54, whichever comes first (3)
- If bleeding occurs when switching to continuous combined HRT and does not settle after three to six months, the BMS suggests switching back to a sequential regimen for at least another year (3). See later FAQ sections; 'Bleeding patterns with HRT and when to refer' and 'Lack of Efficacy, Side Effects'

Ultra Low to High Doses of Oestrogen

Oestrogen dosing

- The British Menopause Society provides a helpful table (copied below) to assist clinicians in selecting the dose of oestrogen and divides oestrogen into different dosing regimes **(3)**
- The table illustrates the different strengths of oestrogen and whether they are licenced or unlicenced.
- The BMS states when HRT is to be used in people over 60 years, lower doses should be started, preferably with a transdermal route of Estradiol administration.
- NICE guidance states 'If a person chooses to take HRT, use the lowest effective dosage' **(1)**.

Table 1: Oestrogen dose from ultra-low, low, standard, moderate, high dose regimens (Reproduced from the BMS) **(3)**

	Ultra-low dose	Low Dose	Standard dose	Moderate dose	High dose
Oestrogel	½ pump	1 pump	2 pumps	3 pumps	4 pumps
Sandrena	0.25 mg	0.5 mg	1 mg	1.5-2 mg	3 mg*
Lenzetto spray	1 spray	2 sprays	3 sprays	4-5 sprays*	6 sprays*
Patch	12.5 µg	25 µg	50 µg	75 µg	100 µg
Oral estradiol	0.5 mg	1 mg	2 mg	3 mg^	4 mg^

* Off-license use
mg = milligrams
^ Off-license use – rarely required to achieve symptom control
µg = micrograms

Progestogenic opposition of oestrogen HRT in people with intact uterus – including off-license use

Levonorgestrel Intrauterine System (LNG-IUS) (Mirena®)

- 52mg LNG-IUS is a good option as the progestogenic arm of HRT (4) and can be used for endometrial protection with ultra-low to high oestrogen dosages for up to five years (3).
- Mirena LNG-IUS is licensed to give endometrial protection as part of HRT for 4 years. FSRH guidance 2023 (5) supports the use **for up to 5 years** (6) outside the product license.
- Although other LNG-IUS products such as Levosert and Benelixa are not licensed for HRT, FSRH guidance supports any 52mg LNG-IUD for endometrial protection as part of HRT for 5 years (5).
- Irregular bleeding is common in first few months of use. Once in situ, periods may reduce by >95% at 6 months and ~20% of users may be amenorrhoeic (7).

Oral Micronised Progesterone

- **Oral micronised progesterone with transdermal Oestrogen may be** associated with lower breast cancer risk (6), although NICE states there is insufficient evidence in this regard (1).
- **This needs to be balanced against risks of endometrial hyperplasia associated with poor compliance** with the oral progesterone.
- Therefore, the best choice of HRT should be individualised after discussion.
- **People taking moderate or high dose Oestrogen** should be informed that the adequacy of endometrial protection provided by micronised progesterone is uncertain (3).

Oral Micronised Progesterone Dose

- **Sequential Combined:** 200 mg taken orally once daily on days 15–26 of each 28-day cycle (**licenced dose)**.
- **Continuous Combined:** 100 mg once daily on days 1–25 of each 28-day cycle (**licenced dose)** or **100mg daily dose (unlicenced dose but supported by BMS)**.
- **Note BMS advises higher progesterone dose if taking high Dose Oestrogen** (3) (See FAQ section 'progesterone type and dosing for endometrial protection for people with a uterus'
- **Note BMS advice on dose for HRT when used with Incretin based therapies for weight loss and diabetes** (8) **(**See later FAQ section)

Progesterone type and dosing for endometrial protection (for people with a uterus)

- People taking moderate or high dose oestrogen should be informed that the adequacy of endometrial protection provided by micronised progesterone is uncertain (3).

- As stated in the Menopause NICE CKS guidance progestogens most commonly used in combined oral HRT are almost all synthetic and include dydrogesterone, medroxyprogesterone, norethisterone, levonorgestrel, norgestrel, and drospirenone. Women vary in their tolerance to progestogens, and changing the progestogen component of combined HRT may be needed if progestogenic adverse effects occur. Micronised progesterone is identical to the progesterone produced in the body.

- Until evidence relating to safety with moderate and high dose estrogen is available, a pragmatic approach needs to be considered, as the risk to breast tissue from increasing the progesterone dose is also unknown (3).

- **British Menopause Society (BMS) guidance recommends a progestogen dose in proportion to the oestrogen dose in people who have a uterus, to reduce unscheduled bleeding and endometrial cancer risk (see table below)** (3)**.**

- **If taking high dose oestrogen or if unscheduled bleeding occurs with ultra-low to moderate dose oestrogen, then the BMS advises 200mg micronised progesterone as a continuous preparation or 300mg as a sequential preparation.** The higher dosing of micronised progesterone is off licence but supported by the BMS.

Table 2: Recommended oestrogen dose per licensed oestrogen dose (reproduced from The British Menopause Society). See previous section for dosing regimes for continuous and sequential (3)

Estrogen dose	Micronised Progesterone		Medroxy progesterone		Norethisterone		LNG-IUD (52mg)
	continuous	sequential	continuous	sequential	continuous	sequential	
Ultra/Low	100 mg	200 mg	2.5 mg	10 mg	5 mg*	5 mg*	
Standard	100 mg	200 mg	2.5-5 mg	10 mg	5 mg*	5 mg*	One – for up to 5 years of use
Moderate	100 mg	200 mg	5 mg	10 mg	5 mg	5 mg	
High	200 mg	300 mg	10 mg^	20 mg^	5 mg	5 mg	

* 1 mg provides endometrial protection for ultra-low to standard dose estrogen but the lowest stand-alone dose currently available in the UK is 5 mg (off-license use of three noriday POP i.e 1.05 mg, could be considered if 5 mg is not tolerated).

^ There is limited evidence in relation to optimal MPA dose with high dose estrogen; the advised dose is based on studies reporting 10 mg providing protection with up to moderate dose estrogen.

Topical Oestrogen for Urogenital Atrophy

- All topical products are considered low dose Estradiol or Estriol. They include vaginal tablets and creams.
- Low postmenopausal oestrogen levels can cause vaginal atrophy and an increased incidence of UTIs. Vaginal oestrogen treats vaginal atrophy and can also prevent recurrent UTI type symptoms in postmenopausal people.
- NICE menopause guideline 2024 states 'offer vaginal oestrogen to people with genitourinary symptoms associated with menopause (including those using systemic HRT)' (1). This is also reflected in the HWE urinary tract infection guidance.
- Creams and pessaries may affect condom integrity.
- All topical vaginal oestrogen can be used in the long term **without adjunctive progestogens** and endometrial monitoring.
- For people with a history of breast cancer, the NICE menopause guideline (2024) (1) has useful information relating to vaginal oestrogen. In addition, advice can be sought from their oncologist and/or a menopause specialist

Topical testosterone for low libido in menopause in adult people on HRT

- **Topical testosterone** (Testogel®/Tostran®) in HWE is recommended for restricted use for people in the menopause with Hypoactive Sexual Desire Disorder (HSDD) / Female Androgen Deficiency Syndrome (FADS) if Hormone Replacement Therapy (HRT) alone is not effective**. HWE Decision Document**
- **Topical Testosterone is AMBER INITIATION in HWE.** Our local GP Fact Sheet – Testosterone gel for people in the menopause details roles for primary care/menopause specialist, information on monitoring and practical guidance on prescribing. Read in full here (9).
- NG23 (Menopause: diagnosis and management 2024) (1) supports HWE position by advising testosterone can be considered for menopausal people with low sexual desire if HRT alone is not effective.
- Before testosterone is considered, people should be fully oestrogenised, and any symptoms of vulvovaginal atrophy adequately treated.

When can Tibolone be considered?

- Tibolone may be considered as an alternative to continuous combined HRT, when first line treatment has not been effective.
- However, it is an Amber Initiation medication which means this is a drug suitable for primary care prescribing following specialist initiation and hence the patient will generally need to be referred for consideration by a specialist.
- Please also note a drug safety update from 2007, www.gov.uk/drug-safety-update/tibolone-benefit-risk-balance which states *'In younger women, the risk profile of tibolone is broadly similar to that for conventional combined hormone-replacement therapy (HRT). For women older than about 60 years, the risks associated with tibolone start to outweigh the benefits because of the increased risk of stroke. Healthcare professionals should weigh the increased risk of stroke with tibolone against the increased risk of breast cancer with combined HRT for women with a uterus.'*

Cautions, Contra-indications and Risks of HRT

- For full list of cautions and contra-indications: see individual product Summary of Product Characteristics.
- Risks of HRT: The MHRA have produced tables to aid communication about risks and benefits **(10)**.
- NICE guideline 2024 has a section on risks and also includes a link to decision aids regarding HRT **(1)**
- BMS has also produced a statement in response to the publication of the updated 2024 NICE guideline (NG23): https://thebms.org.uk/2024/11/bms-statement-in-response-to-the-publication-of-the-updated-nice-menopause-guideline-ng23/ Which is helpful when considering risks.

Can people with migraines use HRT

British Menopause Society has a statement on how HRT can be used in people who have migraines (11).

Key points in the summary include:

- Migraine with aura does not contraindicate HRT.
- Use non-oral oestrogen (patch or gel)
- Use the lowest oestrogen dose that effectively controls vasomotor symptoms.
- Where progestogen is required, continuous delivery is recommended, with preparations such as:
  - levonorgestrel intrauterine system
  - transdermal norethisterone (as part of combined patches)
  - micronised progesterone

Surgical Menopause, including Subtotal Hysterectomy and Endometriosis

This section provides information relating to people who have undergone a surgical menopause (bilateral oophorectomy) during a hysterectomy. The guidance below is based on a BMS Publication, 'Surgical menopause: a toolkit for healthcare professionals' (12). Where clinicians are unsure, advice can be sought from a healthcare professional experienced in the management of menopause.

- All people <45 years old undergoing surgical menopause should be offered HRT at least until age 51 unless there are contraindications (eg a personal history of hormone dependant cancer).
- For those at high risk of ovarian cancer and have had risk reducing surgery AND a personal history of breast cancer there should be a discussion with their breast cancer care team prior to commencing HRT
- Once the average age of menopause has been reached, an informed decision should be made around the ongoing use of HRT depending on the presence or not of menopausal symptoms.
- Oestrogen-only HRT can be used in women without a uterus (hysterectomy). People retaining their uterus MUST receive combined oestrogen and progestogen treatments to reduce the risk of endometrial carcinoma.

For people undergoing subtotal hysterectomy

- Those who have undergone subtotal hysterectomy may have some remaining endometrial tissue which could have a risk of hyperplasia/malignancy with oestrogen only HRT. The BMS article suggests an initial progesterone challenge (two cycles of sequential HRT should suffice) and if no bleeding occurs or pathology reports confirm no remaining endometrium then they can be managed on oestrogen only HRT. Otherwise, long term they will require continuous combined HRT.

For people undergoing surgical menopause due to endometriosis

- Continuous combined oestrogen/progestogen HRT is advised following hysterectomy in people who have widespread endometriosis to reduce the risk of stimulation and malignant transformation of endometrial deposits.
- Changing to oestrogen only at a later date due to a better safety profile can be considered but must be balanced with the risk of reactivating endometriosis and potential malignant transformation of endometrial deposits.
- HRT should be reviewed and suspended if symptoms recur.

For the above scenarios, where clinicians are unsure or need further advice, they should ideally contact the gynaecologist who performed the original operation. Alternatively, they could ask for advice and guidance from a relevant specialist.

Follow up/Annual Review/Duration of Treatment (1), (4)

- **Follow up after three months of starting or changing treatment** to assess effect, enquire about side effects & bleeding pattern **and then at least annually**, unless clinical indications for earlier review (e.g. treatment ineffectiveness or adverse effects).
- **Unscheduled vaginal bleeding** (In people with a uterus) is a common side-effect of HRT within the first 3 months of treatment. See later FAQ sections in this document 'Lack of efficacy, side effects and doses' and 'bleeding patterns with HRT' and 'when to refer'.
- **At annual review**, reinforce lifestyle measures, check efficacy, side-effects, ensure correct dose, optimal route of delivery and compliance. Also check:
  - Pros & cons of continuing. Risk of breast cancer rises with long-term use (use MHRA risk tables (10) to inform discussion)
  - Check BP, encourage engagement with national screening programmes (breast/bowel/cervical) as appropriate.
  - Discuss switching from sequential combined HRT to continuous combined HRT where appropriate.
  - Enquire about symptoms of urogenital atrophy.

  If prescribed testosterone Its recommended that total testosterone, sex hormone binding globulin (SHBG) tests and Free Androgen Index (FAI) estimates should be done prior to starting treatment, then at 3 and 6 months post starting therapy, then **annually**, with blood tests performed sooner if patients have symptoms , see HWE guideline: Testosterone (9).
  Duration of treatment: There are no reasons to place mandatory limitations on duration of HRT. Treatment review (at least annually) should include a well-informed discussion and should consider specific goals and objective estimate of risks and benefits, including advising that risks of breast cancer increase with both age of the woman and duration of use (>5yrs).
  When stopping HRT, offer a choice of gradually reducing or immediately stopping treatment:
    - gradually reducing HRT may limit recurrence of symptoms in the short term.
    - gradually reducing or immediately stopping HRT makes no difference to their symptoms in the longer term.

Lack of efficacy

Causes
Consider the following causes: - Too soon for symptom response - Oestrogen dose not high enough - Poor concordance with treatment - Poor patch adhesion - Limited absorption/metabolism - Symptoms not menopausal

How long does HRT take to work?

Vasomotor symptoms—some improvement after one month, maximum by 3 months. Generally, wait at least 3 months before increasing dose of oestrogen.

Urogenital symptoms— some improvement by 3 months, but may take 6 months

Psychological symptoms—variable response

Side Effects

- Oestrogen and progestogen can both cause side effects and it can be difficult to separate out oestrogen and progesterone side effects as there is quite a lot of overlap.
- Generally, progestogen side effects are more problematic than oestrogen. Note the different groups of progestogens (see below) as some people may tolerate one type better than the other.
- **Breast Tenderness**, **Bloating** and **Bleeding** are the three main side effects.
- **Three months to settle:** Side effects will usually take about 3months to settle, and it is often worth advising continuation to see if they settle.
- **Changing route** from oral to transdermal may be better tolerated.
- **Lowering dose of Oestrogen:** may help, particularly if feels worse or suspected side effects emerge as dose of oestrogen increased or if initially started on higher dose and experiencing suspected side effects.
- **Bloating:** changing progesterone type or swapping to Mirena may help.
- **Bleeding:** Increasing progesterone dose, changing progesterone type, or swapping to Mirena may help. Refer to later FAQ **section on 'Bleeding patterns on HRT and when to refer'.**
- **Ongoing vasomotor symptoms:** Clinician can try increasing the oestrogen. Otherwise can try changing oestrogen to a transdermal formulation.

Menopause, HRT and Contraception

See the Faculty of Sexual and Reproductive Healthcare guidance on 'Contraception for People Over 40 Years' (13) for detailed guidance.

- A woman is potentially considered to be fertile for 2 years after her last menstrual period if she is younger than 50 years of age, and for 1 year if she is over 50 years of age. (1)
- At the present time, Progesterone Only Pill (POP), Progestogen Only Implant (IMP) and depot medroxyprogestrone acetate (DMPA) are not licensed for and cannot be recommended as endometrial protection with oestrogen-only HRT.
- All progestogen-only methods of contraception are safe to use as contraception alongside sequential HRT.
- Combined Hormonal Contraception (CHC) can be used in eligible people under 50 as an alternative to HRT for relief of menopausal symptoms and prevention of loss of bone mineral density but should stop once reach age 50 and use an alternative, safer method.
- Combined oral contraception (COC) containing levonorgestrel or norethisterone should be considered first-line COC preparations for people over 40 due to the potentially lower VTE risk compared to formulations containing other progestogens.
- People who smoke should be advised to stop CHC at age 35 as this is the age at which excess risk of mortality associated with smoking starts to become clinically significant.
- COC with ≤30µg ethinylestradiol should be considered first-line COC preparations for people over 40 due to the potentially lower risks of VTE, cardiovascular disease and stroke compared to formulations containing higher doses of oestrogen.

In patients requiring contraception and who are free of all contraindications, consider offering the following HRT/contraceptive options:

- Oestrogen-only pill, patch or gel and Mirena® coil (see comment in previous section about other intrauterine systems that are not licensed for endometrial protection)
- Combined hormonal contraception (if eligible but only up until age 50)
- Sequential combined HRT (pill or patch) and progestogen-only contraception (tablet, implant, injection)
- If hormonal contraception is declined: advise barrier methods with sequential combined HRT.

When to stop contraception:

- <50 years: 2 years after last period
- >50 years: 1 year after last period
- 45- 55 years: Mirena® after 45 years can stay in until age 55 for contraception and as part of HRT for 5 years only (unlicensed use)
- In general, all people can cease contraception at age 55 as spontaneous conception after this age is exceptionally rare even in people still experiencing menstrual bleeding. If a woman aged 55 or over does not wish to stop a particular method, consideration can be given to continuation providing the benefits and risks for her as an individual have been assessed and discussed with her.
- Do not check FSH if on HRT / combined hormonal contraception.
- If >50 years with amenorrhoea due to progestogen only method and people wish to stop before age 55years (when natural loss of fertility can be assumed for most people)- check FSH: if FSH level >30 IU/L stop after 1 year, if <30 IU/L repeat again in 12 months
- On sequential HRT: contraception required until 55 years
- Detailed advice on when to stop contraception can be found on the CKS 'Contraception Assessment' (14).

Patients using Incretin Based Therapies for Weight Loss and Diabetes

- Please note and refer to the FSRH statement: 'Glucagon-like peptide-1 (GLP-1) agonists and oral contraception' which provides additional advice on precautions to take (15).

Bleeding patterns with HRT and when to refer

NICE guideline on menopause (1) states; Explain to people with a uterus that vaginal bleeding is a common side effect of systemic HRT within the first 3 months of treatment. Advise them to seek medical help promptly if they experience vaginal bleeding after 3 months. [2015] See recommendations on endometrial cancer in NICE guideline [NG12] Suspected cancer: recognition and referral (16).

Refer to two week wait criteria in local guidelines. A majority of patients bleeding on HRT do not need 2 week wait referral.

Exclude other causes by taking full history, full exam (including vaginal exam), and investigations as needed (eg STI investigations).

The BMS guideline Progestogens and endometrial protection states 'for the majority of people with unscheduled bleeding on HRT, modifying progestogen intake often controls the bleeding especially in people who experience unscheduled bleeding in the first few months after commencing HRT' (2)

A recent BMS guideline has produced a flow chart on managing bleeding in people on HRT (3). This is supported by the getting it right first time (17) national programme of work.

The BMS guideline, Management of Unscheduled Bleeding on HRT should be referred to in full with some key points as follows: (3)

- Risk factors for endometrial hyperplasia and cancer should be identified. Major risk factors are BMI ≥ 40 and hereditary conditions such as Lynch or Cowden syndrome. Minor risk factors include BMI 30-39, diabetes, and polycystic ovarian syndrome (PCOS).
- In the absence of risk factors for endometrial cancer, offer adjustments in the progestogen or HRT preparation, for 6 months in total, if unscheduled bleeding a) occurs within six months of starting HRT or b) is persisting three months after a change in HRT dose or preparation.
- **There are some exceptions to the above statement, so the BMS guideline should be reviewed in conjunction with this statement. For example an Urgent transvaginal ultrasound scan is recommended if there are any of the following factors:**
  - **the bleeding is prolonged or heavy**
  - **there are two minor cancer risk factors**
  - **it is more than six months since starting HRT**
  - **it is more than 3 months after a change in dose or preparation.**
- Local two week wait forms can also be referred to and advice and guidance can be sought if needed.

The BMS guideline offers the following advice regarding changing progesterone to reduce unscheduled bleeding episodes

- Assess adherence and understanding of how to use the prescribed preparation including dose and duration of progestogen – for example, would a combined patch or pill reduce administration errors when compared to a separate oestrogen and progestogen components.
- Offer a 52 mg LNG-IUD; this preparation reduces episodes of unscheduled bleeding when compared to all other preparations.
- Oral preparations provide higher rates of amenorrhoea when compared to transdermal preparations and could be offered, if there are no risk factors for thrombosis, as a) a first-line therapy or b) to women who have recurrent unscheduled bleeding with transdermal preparations.
- Offer vaginal oestrogens if there are atrophic findings on examination.

Please refer to previous FAQ sections to help provide guidance on unscheduled bleeding:

- Sequential v Continuous HRT (for people with uterus)
- Progesterone type and dosing for endometrial protection (for people with a uterus)
- Lack of Efficacy, Side Effects

HRT – Managing Supply Chain Issues and HRT Shortages

The BMS website regularly issues updates on HRT supply in its newsfeed News - British Menopause Society (thebms.org.uk). The SPS Medicines Supply Tool provides up to date, timely supply information from the Department of Health and Social Care and Medicines Value and Access Team, NHS England (log in required, free to register).

The following resources give guidance on equivalent options with HRT preparations to support switching in primary care where necessary: **BMS HRT Practical Prescribing**; **BMS HRT Preparations and Equivalent Alternatives and SPS Information Resources for advice on HRT.**

Off Licence Prescribing

Specialists in menopause are increasingly recommending HRT regimens that fall outside current product licenses. The BMS has stated: '*There are no guidelines which recommend that the dose of oestrogen provided should be increased out of license or that different forms of oestrogen should be added together to control symptoms. In the event of a significant event occurring (such as endometrial hyperplasia or cancer) in people using different formulations of oestrogen, outside of license, the prescribing clinicians are responsible for having put patient safety at risk*' and 'H*igher doses of oestrogen require a higher dose of progestogen to ensure adequate endometrial protection* (BMS Tools for Clinicians: Progestogens and endometrial protection)' (2), (18).

The BMS has guidance on progestogens and endometrial protection which includes information on the limited available evidence for off-license routes of administration of oral micronised progesterone here BMS Progestogens and endometrial protection (2). There remains debate about what constitutes high dose oestrogen and there can be significant individual variation in absorption and metabolism.

It is up to individual clinicians in primary care to decide whether they take on (either from a private or NHS specialist recommendation) off-license prescribing responsibility of HRT. They should only do so where satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy given the above guidance. Primary care teams may wish to develop a practice view on this. Informed patient consent and any monitoring and/or follow up treatment should be clearly recorded. This guidance does not endorse off licence prescribing but is designed to provide information to help clinicians to make an informed decision when managing menopausal symptoms.

Private prescriptions:

Some patients may elect to access menopausal services outside the NHS. Responsibility for prescribing rests with the prescriber who has clinical responsibility for a particular aspect of the patient's care. Further/ongoing treatment with a drug, recommended by a private consultant can be continued in primary care providing: the primary care prescriber agrees the treatment is necessary; the drug is listed on the Herts and West Essex (HWE) Integrated Care Board Formulary (19); the drug is normally funded in HWE for that condition. An NHS prescriber can decline a request to prescribe should they feel the treatment does not fall in line with locally agreed decisions/national guidelines or is likely to be beyond the scope of their current clinical practice (i.e., specialist treatment or unlicensed preparations/off-label use). If an NHS prescriber does not feel confident or competent to take over the prescribing responsibility from a private clinician, they are under no obligations to do so. See HWE Guidance on Requests for NHS Prescribing following a Private Consultation (20) on boundaries between NHS/Private treatments.

Prescription Charges

Some HRT medications have multiple prescription charges which are payable where on the same prescription; Different drugs, different formulations or presentations of the same drug or preparation are prescribed and supplied. For example: Evorel Sequi patches attract 2 prescription charges as one box contains both Evorel 50 patches (containing estradiol only) and Evorel Conti patches (containing estradiol and norethisterone). Further information with a non-exhaustive list is available in the following factsheet. To assist patients with the cost of prescription charges, a HRT pre-payment certificate could be utilised.

HRT pre-payment certificate (HRT PPC) is available for patients who pay for NHS prescribed HRT medicine 3 or more times in 12 months and hence the HRT PPC could save money. Each item on an NHS prescription is usually £9.90 (2024-25) and the HRT PPC is a one – off annual payment of £19.80 which covers an unlimited number of prescriptions for eligible HRT medicines for 12 months. Further information for list of medicines the certificate includes and for further information is available on the NHSBSA website.

Use of Incretin Based Therapies for Weight Loss and Diabetes

For women using combined HRT and receiving incretin-based therapies for weight loss or diabetes, such as semaglutide or tirzepatide, clinicians should be aware of concerns over endometrial protection from potentially reduced absorption of oral progestogens due to delayed gastric emptying.

The British Menopause Society has produced some guidance on this which is summarised as follows (8):

1. For people requiring HRT with obesity/overweight with comorbidities and diabetes, the transdermal route for oestrogen is preferred and this is also the case with concomitant use of incretin-based therapies.
2. Incretin-based therapies delay gastric emptying and therefore may reduce the absorption of any oral component of HRT.
    a. Extrapolating data on COC effects indicates that using non-oral progestogen for 4 weeks after initiation and for 4 weeks after each dose escalation with incretin-based therapies may be needed for effective endometrial protection.
    b. From a pragmatic perspective, with several potential dose changes, a non-oral route for the progestogen component of HRT would be preferable throughout treatment with incretin-based therapies.
    c. The 52 mg Levonorgestrel releasing intrauterine device provides contraception during the perimenopause, and endometrial protection for the oestrogen component of HRT, unaffected by concomitant use of incretin- based therapies. This is therefore likely to be the most comprehensive option for endometrial protection when using combined HRT concomitantly with incretin-based therapies for obesity/diabetes (expert opinion).
3. Where oral progestogen is preferred by patients on HRT, there are no data to inform the dose adjustment required for endometrial protection in high-risk women, including those treated with incretin-based therapies.
    a. A potential approach is to temporarily increase the dose of oral progestogen for 4 weeks after commencing incretin-based therapies, and with each dose increment. This is based on extrapolation from COC data and intuitive expert opinion. Uncertainty should be shared with the patient to aid informed decision making.
    b. In the presence of unscheduled bleeding in patients using HRT and incretin-based therapies, national consensus guidance should be followed.
4. Patients who continue to have unscheduled bleeding despite modifying their progestogen intake while using incretin-based therapies, or where there is a concern about the clinical presentation, bleeding amount, or pattern, should be assessed to exclude endometrial pathology. It may be prudent to consider investigations earlier than stated in national guidance in high-risk women (expert opinion).

A pragmatic approach to adjusting progesterone dosing with different HRT preparations, based on limited available evidence, is summarised in box below (reproduced from The British Menopause Society (8)):

Current progestogen	Recommendation
Combined patch	No change
LNG-IUD up to 5 years	No change
Oral progestogen/progesterone*	Consider changing to LNG-IUD/increase dose of progestogen/progesterone at initiation for 4 weeks and for 4 weeks after any dose increment
Vaginal progesterone (off licence)	No change

For women requiring contraception, please note and refer to the FSRH statement: 'Glucagon-like peptide-1 (GLP-1) agonists and oral contraception' which provides additional advice on precautions to take (15).

Further Advice and Clinician Resources

Where can clinicians get further advice?

- Consultant Connect menopause advice line.
- Advice and guidance routes

The RCGP, BMS and PCWHF have educational materials to support primary care in updating knowledge of the menopause:

- RCGP Learning – People's Health Hub https://elearning.rcgp.org.uk/course/index.php?categoryid=57
- BMS Tools for Clinicians https://thebms.org.uk/publications/tools-for-clinicians/
- Primary Care People's Health Forum https://pcwhf.co.uk/resources

Other services

- Weight management - Healthy weight | Hertfordshire County Council, Health and wellbeing services: Weight management | Essex County Council
- Stop Smoking - Stop Smoking Service | Hertfordshire County Council, Health and wellbeing services: Stop smoking | Essex County Council
- Keeping active - Keep active | Hertfordshire County Council, Health and wellbeing services: Physical activity | Essex County Council
- Sexual Health - Home :: Sexual Health Hertfordshire, Health and wellbeing services: Sexual health services | Essex County Council
- Talking Therapies - Referral | HPFT IAPT Services
- Health in Herts - Health in Herts | Hertfordshire County Council, Health and wellbeing services: Overview | Essex County Council

When to Seek advice and/or Refer

Before referring to a specialist, consider advice and guidance by using Consultant Connect Menopause Line or General Advice and Guidance routes.

Seeking advice or referring would include the following scenarios:

- Premature ovarian failure
- Higher risk of breast cancer
- Previous breast cancer (sensible to get oncology opinion in first instance)
- Complex past medical history (e.g. strokes, heart attacks, high risk of cardiovascular disease, lupus) (consider advice and guidance)
- Unable to control symptoms after following guideline (consider advice and guidance)
- Testosterone initiation (e.g. needed after oestrogen/progesterone HRT)

NICE guideline; **Menopause: identification and management (NG23)** (1) has the following suggestions

- For people with a personal history of coronary heart disease or stroke, ensure that combined or oestrogen-only HRT is discussed with and offered, if appropriate, by a healthcare professional with expertise in menopause. [2024]
- In November 2024, use of combined or oestrogen-only HRT in people with active or recent arterial thromboembolic disease was off-label.
- Ensure that trans men or non-binary people registered female at birth who have taken gender-affirming hormone therapy in the past and have symptoms associated with menopause can discuss these with a healthcare professional with expertise in menopause. [2024]

Patient Information

Below are a collection of links that might be helpful to provide to patients. By providing these links, Herts and West Essex ICB do not imply endorsement of these organisations and cannot confirm the factual accuracy of the content contained within the links.

- www.menopausematters.co.uk/menopause.php
- www.peoples-health-concern.org/help-and-advice/factsheets/
- menopausesupport.co.uk – Supporting You Through Change
- Menopause and later life | RCOG
- Rock My Menopause - Menopause Information
- Menopause - NHS (www.nhs.uk)
- Hormone replacement therapy (HRT) - NHS (www.nhs.uk)
- Healthtalk

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Credits also given to

HWE Menopause Prescribing Guidance Bath & NE Somerset, Swindon and Wiltshire Together guidance, Buckinghamshire, Oxfordshire and Berkshire West HRT formulary and Treatment guidance

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