Position Paper

Good Clinical Practice Recommendations for Menopause Care in Pakistan: Pakistan Menopause Society (PMS)

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Executive Summary

Diagnosis: Clinical history is central. In healthy women aged ≥45 years with typical symptoms, menopause is usually diagnosed clinically without laboratory testing. Serum FSH is reserved for suspected premature ovarian insufficiency, early menopause or diagnostic uncertainty. Assessment should address menstrual pattern, symptom burden, quality of life, comorbidities and red flags.

Lifestyle & Psychosocial: Promote balanced nutrition, adequate calcium and vitamin D, regular aerobic and resistance exercise, restorative sleep, weight management, smoking cessation and caffeine moderation. Cognitive Behavioural Therapy, mindfulness, stress management and family support should be integrated where appropriate.

Menopausal Hormone Therapy (MHT): It is the most effective treatment for vasomotor symptoms and supports genitourinary and bone health. Estrogen alone is appropriate after hysterectomy; women with an intact uterus require endometrial protection with progesterone or progestogens. Treatment should be individualized using the lowest effective dose and suitable route.

Non-Hormonal Treatment: Selective Serotonin Reuptake Inhibitor (SSRIs), Serotonin-Norepinephrine Reuptake Inhibitor (SNRIs), gabapentin, oxybutynin and neurokinin-receptor antagonists may be used when MHT is contraindicated or declined. Vaginal moisturizers and lubricants are first line for genitourinary symptoms. Complementary supplements require caution because evidence is limited.

Abnormal Bleeding: Postmenopausal, post-coital, persistent intermenstrual or unscheduled bleeding requires prompt investigation, guided by bleeding pattern, endometrial thickness and individual risk.

Special Populations: Women with premature ovarian insufficiency, early menopause, complex comorbidities or hormone-sensitive cancers require individualized specialist care.

Keywords: Endometriosis; Pakistan; Good Clinical Practice; Pain Management; Fertility Preservation

Cite: Sadia S, Mazhar SB, Hayat Z, Akhtar T, Jabeen S, Tariq N, Muslim Z, Chaudhri R. Good Clinical Practice Recommendations for Menopause Care in Pakistan: Pakistan Menopause Society (PMS). J Soc Obstet Gynaecol Pak. 2026; 16(2):171-185. DOI. 0.71104/jsogp.v16i2.1086

Introduction

I. Menopause occurs 12 months after last menstrual period, preceded by the 'perimenopause'. The average age of menopause in Pakistan ranges between 45 and 49 years which is lower than among the Caucasians. During menopause, declining estrogen may cause physical and psychological symptoms ranging from mild to severe. South Asian data suggests that the early age of menopause may predispose women to chronic health disorders (e.g. cardiovascular disease (CVD), osteoporosis, hypertension, diabetes, dementia, cancers) a decade earlier than their Caucasian counterparts. In Pakistan, an estimated 18–22 million women are aged 45–64 years, a growing population as female life expectancy approaches 70 years.

II. Women may present at menopause with menstrual problems, menopausal symptoms or for a general health checkup allowing opportunistic health screening a chance. The health professional should give appropriate care for both the symptomatic and asymptomatic menopausal women. Information about women's midlife health and menopause is more easily accessible digitally by healthcare professionals (HCPs) while the public gets majority of information from the social media which influences how women perceive menopause experience and seek care.

III. An exhaustive & rigorous review of literature has been undertaken by the Pakistan Menopause Society (PMS) to draft clinical practice recommendations on women's health in the midlife and menopause for the HCPs across Pakistan who are providing support and guidance to women at this critical stage of life. The future of menopause care depends on equipping the OBGYN as well as primary care clinicians with the education and confidence to provide evidence-based care while recognizing when specialty referral is needed. HCPs managing menopausal women should identify menopause specialists for referral of complex cases involving significant medical histories, difficult treatment decisions, persistent symptoms, or unusual circumstances.

IV. The overall aim of this document is to provide the HCPs with latest evidence-based guidance for care of women in the midlife and menopause in Pakistan. These recommendations have been peer reviewed and will be made available online on the PMS website. Sixteen initial drafts, prepared by the authors, were reviewed by experts in collaboration with the PMS Chair. The experts have endeavoured to highlight available medical care in relation to prevalence of conditions and symptom severity in the local country-specific context. In Pakistan, limited availability and licensing of MHT and alternatives as well as attitudes of the public, medical community and health authorities towards menopause care within the resource limitations remains relevant. HCPs consulting this recommendation document should tailor the menopause care approach to the client's circumstances, needs, values and preferences while taking medical history into account before offering treatment. All women deserve treatment with dignity and respect while communicating risks, benefits and consequences of menopause management making shared decision essential.

V. The PMS is grateful to the expert writing group for their efforts to achieve consensus on recommendations and key messages on women's midlife health, menopause and prevention of diseases of aging.

1. Terminology and Definitions

1.1 Staging Framework: To improve comparability of the strategies of management of this universal physiological event, the Stages of Reproductive Aging Workshop +10 (STRAW+10) staging, classifies a woman's reproductive life into seven stages anchored around the final menstrual period (FMP): five stages before the FMP (reproductive years −5 to −3, and menopausal transition −2 and −1) and two after (post menopause +1 and +2). This is based on the menstrual cycle, endocrine parameters and ovarian reserve markers applicable to the vast majority of women, except for those with Premature Ovarian Insufficiency.

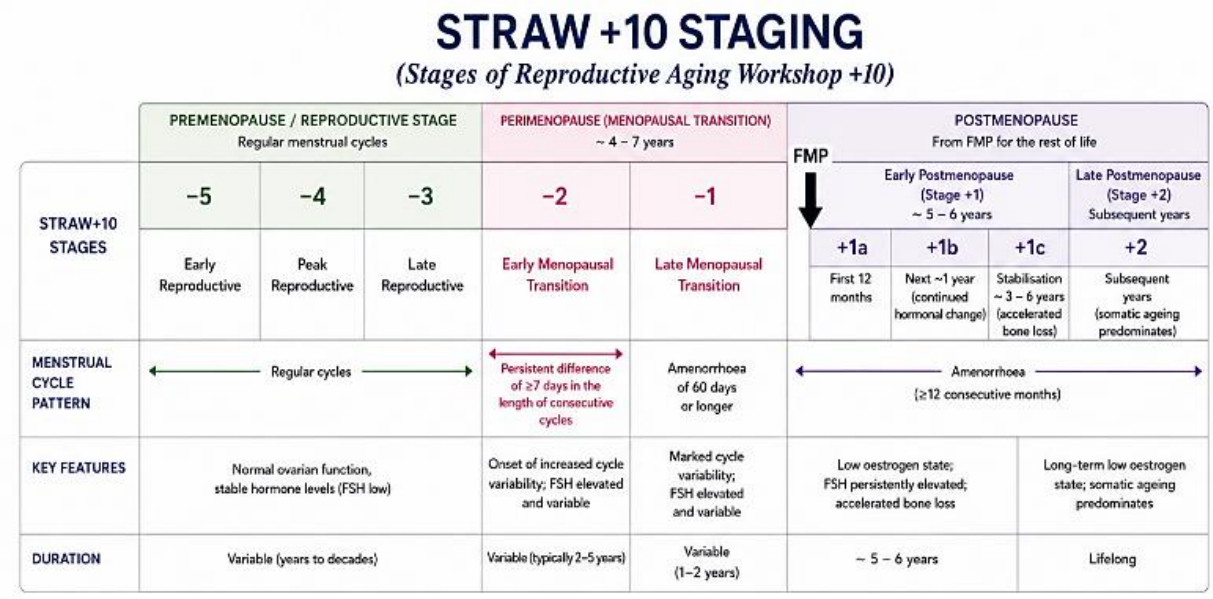

Figure 1. STRAW + 10 Staging.

1.2 Core Definitions

1.2.1 Natural Menopause: Menopause occurring spontaneously due to physiological loss of ovarian follicular activity, recognised after 12

months of amenorrhoea not attributable to any other cause.

1.2.2 Final Menstrual Period (FMP): The date of the last menstrual bleed, which can only be confirmed once 12 months of amenorrhoea have elapsed.

1.2.3 Premenopause / Reproductive Stage: The reproductive period preceding any features of the menopausal transition, characterised by regular menstrual cycles (STRAW+10 stages −5 to −3).

1.2.4 Perimenopause (Menopausal Transition): The period "about or around the menopause," beginning with the onset of menstrual cycle irregularity (a persistent difference of ≥7 days in the length of consecutive cycles — STRAW+10 stage −2) and continuing until 12 months after the FMP (stage +1a). It typically spans approximately 4–7 years.

1.2.5 Early Menopausal Transition (STRAW+10 Stage −2): Onset of increased variability in menstrual cycle length, defined as a persistent ≥7-day difference in the length of consecutive cycles.

1.2.6 Late Menopausal Transition (STRAW+10 Stage −1): Occurrence of amenorrhoea of 60 days or longer, reflecting increasing cycle variability and elevated, variable FSH.

1.2.7 Post menopause: The phase commencing at the FMP and continuing for the rest of life.

1.2.7.1 Early post menopause (STRAW+10 stage +1): The first ~5–6 years after the FMP, subdivided into +1a (first 12 months), +1b (next ~1 year of continued hormonal change), and +1c (stabilization, ~3–6 years), encompassing accelerated bone loss.

1.2.7.2 Late post menopause (STRAW+10 stage +2): The subsequent years in which somatic ageing predominates.

1.2.8 Climacteric: The phase encompassing the transition from the reproductive state to the non-reproductive state, including the perimenopause & extending into early post menopause.

1.3 Premature and Early Loss of Ovarian Function

1.3.1 Premature Ovarian Insufficiency (POI): Loss of ovarian activity before the age of 40 years, characterised by amenorrhea or irregular menstrual cycles with elevated gonadotropins and low estradiol. POI encompasses both spontaneous and iatrogenic causes. The term POI is preferred over "premature ovarian failure" or "premature menopause" because intermittent ovarian activity and occasionally spontaneous pregnancy may still occur. POI affects approximately 3.5% of women.

1.3.2 Early Menopause: Menopause occurring before the age of 45 years (spontaneous or induced), but at or after age 40.

1.4 Induced (Iatrogenic) Menopause

The cessation of menstruation after surgical removal of both ovaries (i.e. oophorectomy), or iatrogenic ablation of ovarian function (i.e. chemotherapy or irradiation.

1.5 Symptom Terminology

1.5.1 Vasomotor Symptoms (VMS): The cardinal symptoms of menopause arising from estrogen-related dysregulation of central thermoregulation (hypothalamic KNDy neurons). A hot flush is a sudden, transient sensation of heat, often over the face, neck and chest, frequently with flushing, sweating and palpitations; when occurring during sleep with sweating it is termed a night sweat.

1.5.2 Genitourinary Syndrome of Menopause (GSM): The collection of symptoms and signs associated with a decrease in estrogen and other sex steroids involving changes to the labia majora/minora, clitoris, vestibule/introitus, vagina, urethra, and bladder. GSM replaced the older terms vulvovaginal atrophy and atrophic vaginitis.

1.5.3 Hypoactive Sexual Desire Disorder (HSDD): Persistent or recurrent deficiency or absence of sexual desire causing marked personal distress or interpersonal difficulty, not better accounted for by another condition.

1.5.4 Neuropsychological / Cognitive Symptoms: Mood changes and the subjective difficulty with memory and concentration commonly described as "brain fog," along with sleep disturbance.

2. Menopausal Symptoms

- Menopause is a normal midlife transition, but symptom burden varies widely.
- Women should be counselled that symptoms may be mild, moderate or severe; may begin before the FMP; and may persist for several years.

- Assessment should focus on symptom severity, duration and impact on sleep, sexual health, mood, work, family life and overall quality of life. (2.1: Table 1)

2.2 Recommended Symptom-Assessment Approach

- Start with open questions, then use a checklist covering vasomotor, menstrual, sleep, mood/cognitive, musculoskeletal, genitourinary and sexual symptoms.
- A structured scale such as the Menopause Rating Scale (MRS) and Menopause-Specific Quality of Life Questionnaire (MENQOL) may support baseline and follow-up documentation.
- Assess impact on daily functioning, including sleep, fatigue, work, prayer / physical activity, intimacy, relationships, mental wellbeing and treatment expectations.
- Discuss management choices through shared decision-making. Provide culturally sensitive counselling; many Pakistani women may not volunteer sexual, urinary or mood symptoms unless asked respectfully in a private setting. (2.2.1: Table 2)

2.3 Red flags requiring evaluation or referral

- Postmenopausal bleeding, post-coital bleeding, unexplained intermenstrual bleeding, or sudden heavy/prolonged bleeding.

2.1 Table 1: Temporal classification for counselling and documentation.

Timing	Main domains	Typical symptoms	Clinical points
(A) Early (perimenopause / Immediate post menopause)	Menstrual; Vasomotor; Neuropsychological; Somatic	Irregular cycles, heavy or infrequent bleeding, amenorrhea (AUB); Hot flushes, night sweats, palpitations; Sleep disturbance, fatigue, irritability, anxiety, low mood, poor concentration, brain fog; Headache, joint and muscle pains, breast tenderness, bloating or weight concern.	Symptoms may start before the FMP. Document bleeding pattern, symptom frequency/ severity, triggers, sleep disruption and quality-of-life effect. Investigate abnormal bleeding rather than attributing it automatically to menopause.
(B)Intermediate (first few years after menopause)	Genitourinary syndrome of menopause (GSM) and Hyposexual desire disorder (HSDD)	Vaginal dryness, burning, irritation, dyspareunia, loss of lubrication; Urinary frequency, urgency, dysuria, recurrent UTI, stress urinary incontinence; Reduced libido, arousal difficulty and orgasmic difficulty.	Ask proactively and sensitively because GSM and sexual symptoms are often under-reported. Explain that GSM is commonly chronic and progressive. It may recur when treatment stops.
(C) Late (long-term implications)	Skeletal, Cardiometabolic, Skin/connective tissue and General ageing concerns	Osteopenia, osteoporosis, fragility fractures, height loss/kyphosis; Dyslipidemia, central adiposity, insulin resistance/metabolic syndrome and cardiovascular risk; Skin dryness/thinning, wrinkling, hair thinning, loss of collagen / elasticity; Frailty and cognitive concerns.	Use the menopause visit for prevention: Check BP, BMI, fracture risk, glucose/ HbA1c, lipids, tobacco use; Lifestyle assessment, muscle strength and physical activity advice. Avoid implying all midlife disease is solely due to estrogen deficiency; age, lifestyle and comorbidities also contribute.

2.2.1 Table 2: Symptom group, Core history, Examination & Key Practice Recommendations.

Symptom group	Key practice points
Core history	Ask/document: age, last menstrual period, current and previous bleeding pattern, pregnancy possibility, contraception use, obstetric and gynecological history, hysterectomy/oophorectomy, previous chemotherapy/radiotherapy, current medicines, complementary remedies, and patient preference regarding hormonal or non-hormonal options
Vasomotor	Ask/document: hot flushes/night sweats; frequency, severity, triggers, sleep interruption, palpitations and effect on work or social life. Explain natural history and options.
Mood, cognition and sleep	Ask/document: low mood, anxiety, irritability, panic, poor concentration, memory difficulty, fatigue, insomnia and night-time awakening. Assess timing with menopause symptoms and screen for clinical depression/anxiety and psychosocial stressors.
Musculoskeletal and body changes	Ask/document: joint/muscle pains, loss of strength, weight gain, central adiposity, fatigue and reduced activity. Encourage resistance exercise, weight-bearing activity, adequate protein, sleep optimization and cardiometabolic risk assessment.
GSM/sexual symptoms	Ask/document: vaginal dryness, burning, dyspareunia, urinary urgency/frequency, recurrent UTI, incontinence, reduced desire/arousal/orgasm. Ask in privacy; refer for persistent pain, recurrent UTI or prolapse symptoms.
Long-term health concerns	Ask/document: fracture history, height loss, falls risk, steroid use, cardiovascular disease (CVD) risk factors, diabetes/hypertension, dyslipidemia, obesity/central adiposity, smoking/tobacco use, migraine with aura, liver/renal disease, VTE, coronary diseases/stroke, breast/cervical screening status, family history of CVD, VTE, osteoporosis and cancer. Provide prevention-focused counselling and screening/referral according to risk.
Baseline examination	Record blood pressure, BMI, and preferably waist circumference. Breast, pelvic, speculum or bimanual examination should be performed only when indicated by symptoms, risk factors, or screening requirements, rather than routinely for every woman.

- Breast lump, nipple discharge, skin change, unexplained weight loss, pelvic mass or persistent pelvic pain.
- Chest pain, unilateral leg swelling, acute shortness of breath, neurological symptoms, or severe new headache.
- Severe depression, suicidal thoughts, psychosis, marked cognitive decline, or symptoms causing major functional impairment.
- Symptoms before age 40 years suggesting premature ovarian insufficiency; early menopause age 40-44 years with distress or fertility concern.

3. Clinical Assessment and Screening before treatment

- The aim of clinical assessment is to identify perimenopause, menopause or premature ovarian insufficiency where applicable.
- Assessment should evaluate symptom burden and treatment suitability, identify red flags requiring investigation, and use midlife care as an opportunity for prevention and screening relevant to Pakistani women. (3.1: Table 3)

3.1 Table 3: Identifying perimenopause and menopause

Clinical situation	Recommendation
Healthy woman aged >=45 years with symptoms	Diagnose clinically without laboratory tests. Perimenopause is likely when new VMS occur with menstrual-cycle change.
Previous hysterectomy	Diagnose based on the pattern and combination of symptoms, particularly VMS, because menstrual criteria cannot be used.
Using hormonal combined estrogen-progestogen or high-dose progestogen contraception	Menopause may be difficult to identify; do not use FSH to diagnose menopause while on these hormones
Age 40-45 years with symptoms and cycle change	Consider serum FSH if confirmation will influence counselling or management. Offer psychological support if early menopause is distressing.
Age <40 years with suspected POI	Evaluate for POI: Diagnostic threshold FSH >25 IU/L on two occasions >4 weeks apart with ≥4 months of oligo/amenorrhea; confirm, assess fertility and long-term health implications, and seek specialist advice where needed.

3.2 Assessment before considering MHT

- Discuss benefits, risks, route, dose, expected duration, alternatives and the possibility that symptoms may recur when treatment is stopped.
- Check for contraindications or need for specialist input: unexplained vaginal bleeding; current/past hormone-dependent malignancy; active or recent arterial thromboembolic disease; VTE or strong thrombophilia history; current pregnancy; severe active liver disease; complex comorbidity or high breast-cancer/CVD risk. (3.3: Table 4)

3.3 Table 4: Investigations and screening.

Area	Recommendations
Menopause diagnosis	No laboratory tests for healthy women aged >=45 years with typical symptoms. Investigate/refer POI and Early Menopause (Table 3; section 3.1)
Bleeding/endometrium	Routine / Opportunistic: Document bleeding pattern at baseline and follow-up, especially if treatment is started. Pregnancy test if relevant. Pelvic USG and endometrial assessment for postmenopausal bleeding, post-coital bleeding, unexplained intermenstrual bleeding, sudden heavy/prolonged bleeding or persistent unscheduled bleeding on HRT.
Cardiometabolic	Routine/opportunistic: Consider fasting glucose or HbA1c and lipid profile according to age, risk and affordability. Investigate and refer if hypertension, diabetes, dyslipidemia, obesity, chest pain, stroke symptoms or high calculated risk. Optimize comorbidities before systemic therapy.
Bone and muscle health	Routine / Opportunistic: ask about relevant long-term health concerns (Table 2; Section 2.3). Investigate/refer assess fracture risk and consider Dual-energy X-ray Absorptiometry (DXA) where available for high-risk women, fragility fracture, POI/Early menopause, prolonged steroids, recurrent falls or marked height loss.
Breast and cervix	Routine/opportunistic: promote health awareness and age/risk-appropriate screening. As will be the advice for other women, cervical cytology sampling at 5-yearly intervals and 3 yearly mammography after the age of 50 years. Investigate/refer: diagnostic breast assessment for lump, nipple discharge, skin/nipple change or high familial risk. Do not delay evaluation of suspicious symptoms.
GSM, urinary and sexual health	Investigate/refer persistent dyspareunia/pain, recurrent UTI not responding to treatment, hematuria, prolapse, incontinence affecting quality of life or suspected malignancy.
Mental health and social context	Investigate/refer severe depression, self-harm risk, psychosis, marked cognitive decline, trauma or safeguarding concerns.

3.4 Follow-up in Menopause Clinic and referral framework

- Review women started on treatment at 3 months and 6 months to assess efficacy, tolerability, adherence, side effects and bleeding pattern; then review annually or earlier if symptoms persist or new risk factors arise.
- At review, reassess BP, weight/BMI, bleeding, breast or pelvic symptoms, ongoing need for contraception, screening status and the woman's

preference for continuing, changing or stopping therapy.

- Refer to a clinician with menopause expertise when symptoms are severe or persistent, MHT is contraindicated, risk-benefit assessment is complex, POI or early menopause is suspected, there is high VTE/CVD/breast-cancer risk, or abnormal bleeding requires work-up.

4. Lifestyle Modification at Menopause and Non-Pharmacological Interventions

Healthcare professionals providing care for women should be able to do informed counselling regarding alternatives to MHT/HRT among women:

- Who prefer not to take MHT or are not responding to MHT.
- Where the side effects of MHT outweigh the benefits
- Where MHT is cautioned in specific medical conditions e.g. hormone-sensitive cancers, catamenial epilepsy and unstable lupus etc

Lifestyle optimization is the essential foundation for all menopause care — before, alongside, or instead of pharmacotherapy.

4.1 Key challenges shaping management in Pakistan

- Early age of menopause.
- Endemic vitamin D deficiency; high osteoporotic burden; limited physical exercise
- Low literacy, stigma and taboos
- No dedicated menopausal clinics

4.2 Domains of lifestyle medicine in menopause

- Lifestyle modification's role spans prevention, treatment, prognosis, and quality of life. Prevents metabolic syndrome, reduces cardiovascular risk, improves bone density, enhances mental health & sexual wellbeing.
- There are six key domains of lifestyle medicine in menopause namely healthy eating, physical activity, restorative sleep, mental wellbeing, avoid risky substances and supportive relationship. (4.2.1: Table 5), (4.2.2: Table 6)

4.2.1 Table 5: Healthy Eating.

Area	Recommendations
Balanced Diet	Whole grains, lean protein (dals, legumes, fish, eggs), and healthy fats (olive/canola oil, nuts, seeds). Applicable to Pakistani cuisine: encourage spinach (saag), fenugreek (methi), lentils (e.g. moong dal), chick peas (channa), cornmeal bread (makkai ki roti). The Mediterranean diet suits our population's palate.
Calcium	Daily requirement of calcium for postmenopausal women is 1000-1500 mg/day, it is taken by its sources like milk, yogurt, cheese, fortified food. Calcium supplements are required if the diet is deficient of it
Vitamin D	400 to 600 IU/day is strongly indicated in Pakistan due to indoor lifestyle and purdah, 25(OH) Vitamin D should be regularly checked where feasible and aim for > 50nmol/L .
Phytoestrogens:	Soy-based foods (soya milk, tofu) and flaxseed may modestly ease vasomotor symptoms
Limit/ Avoid	White rice, white flour (maida) based breads, sweetened drinks and colas drive central obesity and metabolic risk — counsel specifically in the context of Pakistani dietary habits
Hydration	Adequate fluid intake (6–8 glasses/day); limit tea excess, which may worsen hot flushes and reduce calcium absorption.

4.2.2 Table 6: Physical Activity.

Exercise Type	Guidance	Recommended time
Moderate aerobic activity	Brisk walking, swimming, cycling	At least 150 minutes /week
Strength/ resistance training	Body weight exercises, Free weight exercises, resistance band exercise	2 to 3 sessions /week
Weight bearing exercise	Essential for bone health — walking, low-impact aerobics; particularly important given high osteoporosis burden	2 to 3 sessions /week
Flexibility and balance	Yoga, a type of resistance exercise focusing on flexibility, balance and mental relaxation	Regular practice
Regular physical activity is endorsed with evidence for cardiovascular protection, bone preservation, mood improvement, sleep quality, stress and psychosocial and vasomotor symptom relief. It improves muscle strength and flexibility and reduces sarcopenia.		
Weight loss of 5–10% is sufficient to improve many abnormalities associated with the insulin resistance syndrome		

4.2.3 Restorative Sleep

- Refers to good-quality sleep that improves daytime alertness, mood, energy and overall well-being.
- Sleep Hygiene: Maintain a regular sleep schedule, avoid screens and heavy meals 2–3 hours before bedtime, limit evening caffeine and alcohol, and keep the bedroom cool, quiet and dimly lit.
- Managing Night Sweats: Wear lightweight, absorbent nightwear, use cooling aids (facial spray,

cold pillow pads), avoid hot drinks and sudden temperature changes, and dress in adjustable layers.

4.2.4 Mental Wellbeing. In Pakistan mental problems are often under-recognized due to cultural stigma. Reducing stress, improving sleep hygiene and mindful practices can improve mental health

4.2.4.1 **Cognitive Behaviour Therapy (CBT):** Recommended for both vasomotor symptoms and mood disturbance. Available in face-to-face, group, or remote formats; self-help CBT resources should be offered where specialist access is limited. Menopause-specific CBT programmes show particular benefit. Sleepio is a digital self-help program that incorporates CBT and is available online.

4.2.4.2 **Mindfulness-based interventions**: Practical, low-cost, and culturally adaptable. Can be delivered in community or primary care settings. Hypnotic induction may reduce hot flushes & improve sleep.

4.2.4.3 **Paced respiration:** Simple breathing exercises are evidence-based for reducing hot flush frequency and intensity.

4.2.4.4 **Psychosocial support:** Involve family members in counselling — in Pakistan's family-centred culture, spousal and family support is a powerful determinant of women's health behaviour.

4.2.4.5 **Acupuncture:** May have a role for reducing flush intensity and reduction in aromatase-induced arthralgia especially in breast cancer survivors.

4.2.4.6 **Screening:** Use validated tools (PHQ-9, GAD-7) to screen for depression and anxiety at menopause consultations.

4.2.4.7 **Therapeutic Rituals & Regulation:** Daily Islamic practices function as built-in mechanisms for emotional regulation:

Salah (Prayer): Provides five mandatory "mindfulness breaks," promoting grounding, rhythmic breathing, and a sense of routine.

Dhikr (Remembrance): Chanting and repetitive remembrance of Allah can lower the heart rate and induce a state of physiological calm, like modern mantra-based meditation.

Dua (Supplication): Acts as a form of "spiritual journaling" or verbal processing, allowing the individual to articulate their deepest fears and hopes to a Divine Listener.

4.2.5 Table 7: Avoid Risky Substances.

Substance	Evidence based advice	Pakistan context
Smoking cigarettes, Naswar, shisha	Cessation: reduces vasomotor symptoms, improves bone density, lowers CVD and cancer risk	Naswar use common in KPK; shisha perceived as less harmful - address both.
Alcohol	Worsens hot flushes, impairs sleep, elevates breast cancer risk. Keep within safe limits if used	Largely absent in observant Muslim population. Address in secular or minority contexts if relevant
Excessive caffeine	May aggravate hot flushes and fragment sleep; advise moderation	Chai consumption is high in Pakistan (4-8 cups/day common); counsel specifically on timing and quantity
Avoid ultra processed foods. Choose personal care products wisely and prefer those made from natural ingredients and minimally processed		

4.2.6 Supportive Relationship: Husband and family support plays an important role in managing menopausal symptoms. Helpful measures include honest communication about hormonal changes, respect for sexual health and personal space, shared healthy lifestyle habits, joint stress management, encouragement of positive body image, and seeking professional help without stigma.

5 Menopause Hormone Therapy (MHT)

MHT is the preferred international term while the term HRT remains in common use. It includes estrogens, progestogens, combined therapies, androgens, and tibolone.

5.1 Indication for MHT

- The primary indication for MHT includes the beneficial effects of estrogens on relief of menopausal symptoms, treatment of GSM, and maintenance of bone health.
- MHT therapy is also indicated and recommended in POI and early menopause.

5.2 Contraindications for MHT

- Endometrial cancer, gynaecological hormone-dependent cancers, breast cancer, high risk for breast cancer
- Active liver disease with abnormal liver function, chronic stable liver disease
- Known current venous thromboembolism (VTE), known thrombophilia, unconfirmed personal or a strong family history of VTE
- Established CVD and at severe increased risk of CVD, migraine with aura

- Known or suspected pregnancy
- Large uterine fibroid
- Undiagnosed abnormal vaginal bleeding

5.3 MHT Regimens

- Estrogen-only regimens
- Sequential combined regimens (scHRT)
- Continuous combined regimens (ccHRT)
- Synthetic steroidal alternatives, e.g. Tibolone

5.4 Selection of MHT regimen: Factors which determine the type and dose of MHT include patient preference, uterine presence or absence, contraceptive needs, symptom type, severity, and any comorbidities.

- Estrogen-alone MHT is given to hysterectomized women.
- Micronized progesterone or synthetic progestogens are added in regimens for non- hysterectomized women to reduce the increased risk of endometrial hyperplasia and carcinoma which occurs with unopposed estrogen.
- Women who use low-dose vaginal estrogen for GSM do not need added progestogen.

Table 8: Combined MHT Regimens.

Regimen	Components	Withdrawal Bleeding
Sequential Combined Cyclical MHT	Estrogen daily plus progesterone/ progestogen for 10-14 days every 28-30 days cycle	Short exposure to progesterone/ progestogen with cyclical withdrawal bleeding
Sequential Long Cycle MHT	Estrogen daily for 12 weeks plus progesterone/ progestogen added in the last 10-14 days	Higher dose, less frequent exposure to progesterone/ progestogen with withdrawal bleeding every 3 months
Continuous Combined MHT	Estrogen plus progesterone/ progestogen administered together continuously	Continuous exposure to progesterone/ progestogen No withdrawal bleeding
Continuous progestogen regimen: Tibolone	Synthetic steroid with estrogenic, androgenic and progestational activity	Continuous exposure to progesterone/ progestogen No withdrawal bleeding

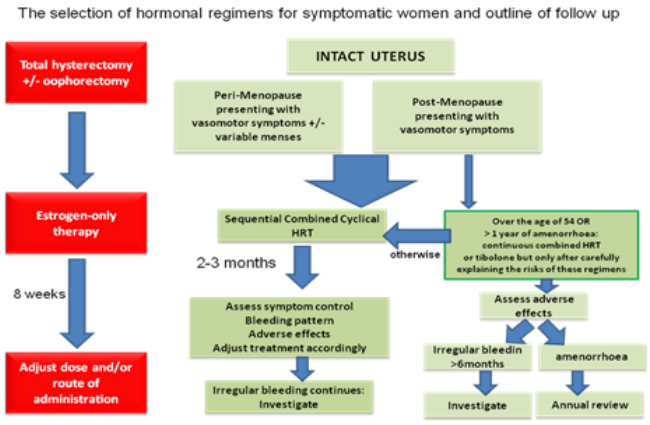

Figure 2: Selection of hormonal regimen

5.5 Types of Estrogens

- There are four types of estrogens which occur naturally in human beings; Estrone, Estradiol, Estriol and Estetrol. Estrone and Estriol are biologically weaker estrogens than Estradiol, but these are not marketed globally for systemic MHT.
- Systemic MHT approved by FDA conventionally contains estradiol, estradiol valerate and conjugated equine estrogens (CEE).
- Vaginal MHT typically has estradiol, estriol, CEE & Dehydroepiandrosterone (prasterone).
- Use of transdermal estradiol (patches/gels/sprays) has reportedly reduced risk of VTE.

Table 9: Dose of Estradiol & Progestogen/Progesterone.

Estradiol.			
Administration route	**Optimal dose**	**Administration route**	**Ultra-low dose**
Oral	1-2 mg	Oral	0.5 mg
Transdermal	0.5 mg	Transdermal	14 µg
Patches	25-50 µg		
Gel	1-2 pumps		
Progesterone/progestogen			
Micronized progesterone	200 mg	Micronized progesterone	100 mg
Dydrogesterone	10 mg	Dydrogesterone	6 mg

5.6 Tibolone (Selective Tissue Estrogenic Activity Regulator—STEAR): Tibolone is a synthetic steroid which has tissue-specific estrogenic effects, acting like estrogen in the brain, vagina and bones to relieve vasomotor symptoms, reduce bone loss and support sexual well-being, while having minimal or opposing effects on the breast and endometrium. It generally does not require additional progestogen, causes less uterine bleeding and may improve mood and libido.

5.7 Selective Estrogen Receptor Modulator (SERM): A compound that exerts tissue-selective oestrogen-receptor agonist or antagonist activity (e.g. raloxifene, bazedoxifene, ospemifene). Ospemifene alone for vulvovaginal atrophy in women who are unable to or do not wish to use vaginal preparations.

5.8 Tissue-Selective Estrogen Complex (TSEC): The pairing of a SERM (bazedoxifene) with conjugated oestrogens (Duave) for women who cannot tolerate progesterone, provide oestrogenic symptom and bone benefit while protecting the endometrium and breast without a progestogen.

5.9 Testosterone: The current recommendation is to start conventional MHT and ensure that the women are adequately estrogenized — especially vaginally before considering adding testosterone administration for persistent HSDD symptoms.

5.10 Body-identical (regulated bioidentical) hormones: Pharmaceutical-grade preparations structurally identical to endogenous human hormones (e.g. 17β-oestradiol, micronized progesterone), licensed and quality-controlled, hence recommended.

5.11 Compounded bioidentical hormone therapy (cBHT): Custom-compounded, unregulated preparations of variable dose and purity, thus not recommended by the BMS, IMS as well as PMS owing to lack of regulation, evidence and safety data.

5.12 Prescribing MHT:

- It is important to adhere to the principle of prescribing at the minimum effective dose of MHT to lower likelihood of adverse estrogen effects (e.g. breast tenderness, bloating, bleeding problems) including a lower risk of VTE and stroke. The risk of VTE is further reduced with transdermal route for estrogen.
- Higher doses of estrogen may be required in women with premature ovarian insufficiency (POI) and early menopause
- The levonorgestrel intrauterine system for progesterone delivery is another way of providing effective endometrial protection as well as contraception with less side effects and better compliance. The LNG-intrauterine system is associated with a doubling of the risk of breast cancer when used with estrogens and should not be used in women with history of breast cancer.
- Timing Hypothesis ("Window of Opportunity"): The concept that the benefit–risk balance of MHT is most favourable when initiated in women younger than 60 years or within 10 years of menopause onset, particularly regarding cardiovascular outcomes.
- Initiation of MHT after the age of 60 years is generally not recommended because of the potential for increased risks of venous thromboembolism (particularly with oral MHT) and stroke.
- Likewise, the use of MHT as a first-line therapy for the treatment or prevention of osteoporosis in women aged 60 years and older is not advisable.
- Where MHT is considered appropriate in women aged 60 years and older, very low-dose regimens should be used, preferably as transdermal estrogen, to minimize adverse effects e.g 25 µg estradiol patches or gel, combined with micronized progesterone 100 mg or dydrogesterone 5 mg for endometrial protection.

5.13 Current Contraception – if the woman requires contraception

- Continue contraception for one year after the last menstrual period in women over 50 years old, or for two years in women under 50 years old.
- Women taking MHT should use barrier methods, an intra-uterine device, or the LNG-IUS if withdrawal bleeding is heavy and cannot be regulated.
- Women taking combined oral contraception may have to change to conventional MHT after the age of 50.

5.14 When should MHT be stopped?

- There is now broad consensus among national and international menopause societies that no arbitrary limits should be imposed on the duration of MHT.
- The decision to continue therapy should be individualized and made jointly by a well-informed woman and her healthcare provider, based on specific treatment goals and an objective assessment of the ongoing benefits and risks for each individual.

5.15 Table 10: MHT products currently available in Pakistan.

Brand Name and Pharma	Ingredients	Type	Route of administration
Climen (Bayer)	Estradiol valerate 2mg, Cyproterone acetate1mg	Sequential Combined	Oral
Progyluton. (Bayer) Estranor (Saffron)	Estradiol valerate 2mg Norgestrel 0.5 mg	Sequential Combined	Oral
Progynova	Estradiol valerate 2mg	Estrogen alone	Oral
Menorin Excel	Conjugated estrogen 0.3 mg	Estrogen alone	Oral
Duavee, Pfizer on line	Conjugated estrogen 0.45mg / Bazedoxifene 20mg (CE/BZA)	Conjugated estrogen plus tissue selective bazedoxifene	Oral
Osfena on-line (Cenrjy Pharma)	Ospemifene 60 mg	SERM	Oral
Tibol (OBS) Lobion (Platinium) Tibopause	Tibolone 2.5mg	Estrogenic, progestogenic, androgenic	Oral
Oestrogel OBS Pharma	Estradiol 0.06 % gel 80 gm	Estrogen	Transdermal
Testiva Aspin	Testosterone Gel 1% sachet (50 mg/5 gm)	Testosterone	Transdermal
Estromarin, Premarin. online	Conjugated Estrogen 0.625 mg/g	Estrogen	Vaginal
Mirena IUS Bayer	Levonorgestrel (LNG) 52 mcg released at 21 mcg/day for 5 years	Progesterone alone	Intra Uterine System
Ovaflow, Nutrasterone	DHEA 25mg	dehydroepandrosterone	Oral
Femoston Abbott	Estradiol and dydrogesterone (previously available, awaiting reintroduction in 2027)	Estrogen & progestogen	Oral

6 Non-hormonal treatment options

Nonhormonal pharmacological therapies are highly effective, evidence-based interventions recommended for managing VMS, GSM and osteoporosis. Nonhormonal options serve as the primary line of medical treatment for women with contraindications to MHT and for those who prefer to avoid hormonal intervention. (6.1: Table 11)

Procedural therapy: Stellate ganglion blockade involves the injection of an anesthetic agent at the lower cervical or upper thoracic region, where the stellate ganglion is located (C6-T2) region of the anterior cervical spine. VMS reduction has been observed in small trials, but skilled operators are required to perform it.

6.2 Non-hormonal treatment for GSM: Vaginal lubricants and moisturizers are considered first line treatment for GSM. Water and silicone-based preparations are preferred over glycerine-based variants. Moisturizers can be used on a regular basis, rather than episodically with sexual activity, daily or several times per week to provide longer lasting effects as they rehydrate the vaginal tissues and mimic vaginal secretions.

Vaginal lubricants and moisturisers available locally

- Kegael Gel (water based) by MKM
- Sretto-V intimate moisture (water based) by Bristol Mayer Biotech
- OVA Gel Personal Lubricant (water based) by Galaxy Nutraceuticals
- Inno KY Jelly/ Durex Personal Lubricant (water based) by Inno/Reckitts
- Gynofit Moisturizing Vaginal Gel (lactic acid based) by Gynofit (imported)

6.3 Flibanserin for Hypoactive sexual desire disorder, a centrally acting serotonergic modulator that functions as an agonist at 5-HT1A receptors and as an antagonist at 5-HT2A receptors, has recently been FDA approved in naturally menopausal women. Dose oral 100 mg daily (Addyi, Fliba 100 mg tablets).

6.4 Non-hormonal treatment options for osteoporosis

- Antiresorptive agents include bisphosphonates (alendronate, risedronate, ibandronic acid, zoledronic acid), denosumab, romosozumab, selective estrogen receptor modulators (raloxifene and bazedoxifene) and anabolic agents include parathyroid hormone preparations (teriparatide and abaloparatide).
- Stratification of the risk of fracture by FRAX into low, high or very high is helpful in decision-making for the need and type of therapy.
- Duration and the sequence of drugs and drug-free periods are drug-specific.
- Anabolic and anti-resorptive therapy should not be routinely combined.
- In sequential therapy, anabolic therapy should preferably be given before anti-resorptive drugs.

Non-estrogen treatments are mainly used in women aged over 60 years because of lack of data in younger women

6.1 Table 11: Non-hormonal therapies for VMS						
Category	**Medication / Treatment**	**Dose / Administration**	**Duration / Efficacy**	**Side Effects**	**Contraindications**	**Notes**
Neurokinin receptor antagonists	Fezolinetant NK3 receptor antagonist for moderate to severe VMS FDA approved	45 mg orally once daily at the same time with or without food	Effective through 52 weeks	Abdominal pain, diarrhea, insomnia, fatigue, ↑LFTs	Avoid in cirrhosis, severe renal impairment, concomitant use of CYP1A2 inhibitors	Baseline LFTs before initiation, LFT routine monitoring at months 1,2, 3, 6, & 9. Fezlon (Nabiqasim) Tab 45 mg
	Elinzanetant dual receptor antagonist NK1, NK3 for moderate-to-severe VMS FDA approved	60 mg orally once daily at bedtime	Effective through 52 weeks	Headache, fatigue, somnolence, nausea.	Improves sleep and menopause-related quality of life	Lynkuet (Bayer, Unavailable; not yet registered with DRAP) Cap 60 mg
SSRI	Paroxetine mesylate FDA approved	7.5 mg at bedtime	6 months to multiple years with periodic reassessment	Nausea, dry mouth, drowsiness, sexual dysfunction	Contraindicated with tamoxifen	must be tapered gradually upon discontinuation to prevent withdrawal. Seroxat (GSK), Paroxin CR 12.5 mg (Amarant)
	Escitalopram. FDA approved	10–20 mg daily		Dizziness, vivid dreams, nausea, sweating		Monitor tolerance. Citanew (Hilton), Zavget (Getz)
SNRI	Venlafaxine / Desvenlafaxine off-label management of moderate-to-severe VMS.	37.5–75 mg daily / 150 mg daily	1–3 years with continued evaluation	Hypertension, nausea, constipation, insomnia less commonly seen with lower doses 37.5mg and 75 mg	Caution in elderly due to hyponatremia / hypotension	Discontinuation needs slow taper off over several weeks. Efexor XR (Wyeth), Velax (Zaka Pharma), Vaxor (Global) 37.5 mg & 75 mg. Denla XR 100 mg (Organic), Lafaxine (Genix), Venadex ER (Genetics)
Gabapentinoids	Gabapentin Off-label treatment of nocturnal VMS and severe sleep fragmentation	300–900 mg daily titrated gradually	6–12 months	Drowsiness, edema, grogginess, unsteadiness, GIT issues	–	Administered at bedtime to counter daytime sedation, discontinuation requires gradual step down. Neurontin (Pfizer), Gabix (Getz), Neupentin (Highnoon) 100 mg, 300 mg, 400 mg
Anticholinergics	Oxybutynin Off-Label for VMS	2.5–5 mg twice daily or 15 mg ER	Effective for hot flush reduction	Dry mouth, constipation, dizziness	Avoid in women ≥65 years	good choice for women with overactive bladder symptoms and VMS. Butyn (Medicaid), Oxynin (Venus)

Table 12: Non-hormonal options for osteoporosis.

Category	Medication / Treatment	Dose / Administration	Duration / Efficacy	Side Effects	Contraindications	Notes
Bisphosphonates. FDA approved	Zoledronate (Aclasta 5 mg/100 ml); Alendronate (Reventa (Getz), Fosamax (Searle) 10 mg); Risedronate (Actonel (Sanofi), Risonate (Shaigan), Bone (Akson) 5 mg, 35 mg, 150 mg); Ibandronate (Ibandro (Pharmevo), Adronil (Searle) 150 mg)	IV yearly or Oral weekly/monthly	drug free period after 3 years of annual IV therapy and 5 years of oral therapy	GI upset, headaches and musculoskeletal pain, flu-like symptom (with zoledronate infusion)	GFR should be >35ml/min prior to the initiation of treatment	Restarting treatment based on FRAX values determined after 18 months of risedronate and ibandronate, 2 years of alendronate, and 3 years of zoledronate. After 10 years of BPs patient management should be considered on an individual basis.
Monoclonal antibody. FDA approved	Denosumab (Prolia-equivalent (Searle) 60 mg/1 ml injection)	60 mg SC every 6 months	Long-term up to 10 years	Hypocalcemia, eczema, cellulitis		Alternative therapy needed after 6 months of last injection
Anabolic agent FDA approved	Teriparatide (Forsteo (Eli Lilly) 20 mcg/80 µl penfill injection)	20 µg SC daily	Limited to 24 months	Headache, nausea, dizziness, postural hypotension		Upon discontinuation follow with anti-resorptive therapy due to rapid bone loss
	Abaloparatide (Not available in Pakistan)	80 µg SC daily	Limited to 18 months	Hypercalcemia, dizziness, palpitations	Contraindicated in severe renal impairment	
Sclerostin inhibitor. FDA approved	Romo sozumab (Evenity (Amgen) 105 mg prefilled syringes)	210 mg SC monthly	Maximum 12 months	Hypocalcemia risk	Avoid if MI or stroke history	

6.5 Complementary Therapies: Over the counter (OTC) supplements should be used with caution, as robust evidence supporting their safety and effectiveness is limited.

- **Pollen Extract:** Has no estrogenic activity and may reduce hot flushes, sleep disturbance, low mood, irritability and fatigue.
- **Turmeric and Vitamin E:** May reduce hot flushes, while turmeric may also relieve knee osteoarthritis pain; neither appears to improve anxiety or sexual function. High-dose turmeric should be used cautiously with anticoagulants. Vitamin E may be obtained from supplements (15 mg/day) or foods such as plant oils, nuts, seeds, spinach and broccoli.
- **Omega-3 Fatty Acids:** Found in oily fish, walnuts, chia seeds, spinach and eggs; dietitians commonly recommend about 1 g/day.
- **Tamoxifen Interaction:** High-dose turmeric (>1,000 mg), vitamin E and omega-3 supplements may individually reduce tamoxifen's protective effect on breast tissue.
- **Isopropanolic Black Cohosh (iCR):** Doses of 40–80 mg may improve mood, sleep and hot flushes, with effects reported as comparable to low-dose estradiol. However, long-term randomized evidence and its interaction with tamoxifen remain unclear.
- **Sage (White Sage):** May reduce the frequency and severity of hot flushes. It should be avoided in women with epilepsy and used cautiously in those with estrogen-sensitive cancers because of possible estrogenic effects.
- **Milk Thistle (Silybum marianum):** May help reduce hot flushes but can interact with medicines metabolized by the liver, including anticoagulants. It is not recommended for women with hormone-sensitive cancers or those receiving endocrine therapy.
- **Ginseng:** May reduce hot flushes and improve quality of life. Asian (Panax) ginseng has

estrogenic activity and should be avoided in women with hormone-sensitive conditions.

7 Symptom wise treatment options

Regardless of treatment requirement, advise on lifestyle adjustments, education on healthy ageing and reassurance.

7.1 Vasomotor Symptoms in Menopause

7.1.1 If no contraindication and eligible, most effective first line pharmacologic option is MHT.

- Best if < 60 years or < 10 years since menopause.
- Estrogen & Progestogen in women with intact uterus; Estrogen alone post hysterectomy.
- Improvement may start in two weeks (low dose: 3- 4 weeks), > 80% improve by 3 months.
- If inadequate response, MHT optimization by dose adjustment, change of formulation or alternative route of administration (prefer transdermal if high risk: obesity, hypertension, migraine, metabolic syndrome, high VTE risk).

7.1.2 In resistant or specific cases, second line options include tibolone and stellate ganglion block (specialist use). In patients with breast cancer, clonidine or SNRIs (venlafaxine) may be considered.

7.1.3 Monitoring ongoing therapy for benefits versus side effects. Individualize continuation. When discontinuing MHT, gradually taper over 3-6 months and monitor for recurrence.

7.2 Neuropsychological Symptoms During Menopause

- Women with a previous history of depression or anxiety are at increased risk of worsening symptoms during the menopausal transition.
- Cognitive Behavioural Therapy (CBT), stress management interventions, support groups, psychoeducation play an important role.
- MHT may improve mood, sleep, and quality of life, especially when symptoms are associated with vasomotor symptoms.
- Antidepressants or anxiolytics for moderate-to-severe mood disorders after appropriate evaluation by specialist.

7.3 Perimenopausal and Postmenopausal Abnormal Uterine bleeding

- Unscheduled bleeding in menopausal women is a red-flag symptom requiring urgent, structured evaluation.
- Endometrial cancer: More than 90% of cases occur in women aged over 50 years, and approximately 10% of women presenting with postmenopausal bleeding (PMB) are diagnosed with endometrial cancer.
- The FIGO classification, PALM-COEIN, is useful for approaching differential diagnosis of abnormal uterine bleeding. Causes may be multifactorial, also rule out gastrointestinal or urinary tract bleeding and metastatic disease, especially in older women.
- A comprehensive history encompassing all the differentials and risk factors along with systemic and pelvic examination are critical.

7.3.1 **Investigate if red flag features identified**

- Suspected malignancy (Postmenopausal bleeding PMB, Post Coital Bleeding PCB, Intermenstrual bleeding IMB, pelvic mass, cervical lesion)
- Structural pathology suspected/identified
- Failed medical treatment
- Erratic bleeding while on tamoxifen
- Heavy, prolonged or breakthrough bleeding for >3 months of commencing scMHT
- Any bleeding after 6 months of cc MHT even in low-risk women
- Bleeding after amenorrhoea has been established in women on MHT
- Any bleeding in the first 6 months if significant risk factors present

7.3.2 **Key Investigations**

7.3.2.1 **Transvaginal pelvic ultrasound for Endometrial Thickness ET & features**

- Sliding sign, focal lesion & feeding vessel
- If the ET is very thin, cause may be endometrial atrophy
- PMB + ET is < 4 mm still 1–2% risk of EC
- If on sequential combined (sc) MHT, measure ET within a week of taking the last progestogen pill

7.3.2.2 **TAS to compliment TVS if enlarged uterus or pelvic mass**

7.3.3 Explain to patients that an endometrial thickness of ≤ 4 mm carries a >99% negative predictive value for ruling out endometrial cancer but still endometrial biopsy is advised adopting initial combined approach.

7.3.4 **Initial Combined Approach:** Aggressive cancers (such as type II endometrial tumours) can occasionally present with a thin

endometrium. Both TVS and endometrial sampling can be done for most patients to avoid missed or delayed diagnoses in the local context where follow up is patchy.

7.3.5 **Exceptions for TVS Alone:** TVS alone can be used for the initial evaluation of select patients if they meet **all** the following criteria:

- Have only a single episode of bleeding.
- Have a sonographically fully visualized endometrium of ≤ 4 mm.
- Lack risk factors strongly associated with endometrial cancer (e.g., obesity, unopposed estrogen therapy).
- Has ready access and willingness to prompt follow-up gynaecologic care.

7.3.6 **Incidental Finding** of > 4 mm discovered incidentally in an **asymptomatic** postmenopausal patient does not routinely require evaluation, unless indicated by individual risk factors.

7.3.7 **Depending on the pelvic ultrasound**

- Hysteroscopy
- Endometrial biopsy: either hysteroscopic guided or pipelle
- Ovarian tumour markers if ovarian neoplasm is suspected

7.3.8 **Indications for endometrial biopsy & histopathology**

- ET ≥4mm in postmenopausal women
- In postmenopausal women with ET < 4 mm if other historical, clinical or sonographic risk factors are present with persistent/recurrent PMB
- ET > 16 mm in premenopausal women
- Persistent IMB
- > 45 years with heavy menstrual bleeding HMB
- Erratic bleeding with Tamoxifen therapy
- Cervical smear with atypical glandular cells of endometrial cell origin

7.3.9 **Criteria for endometrial biopsy for women on MHT**

- Endometrial thickness (ET) >5 mm on cc MHT and ET >7 mm on sc MHT
- Focal lesions on transvaginal ultrasound
- Incomplete visualization or fragmentation of endometrial echo on scan
- Multiple bleeding episodes
- High-risk group with risk factors for endometrial disease or cancer (e.g. raised body mass index, family history of hereditary nonpolyposis colorectal cancer)

7.3.10 **Indications for Hysteroscopy and Biopsy**

- Inadequate Pipelle sample
- Persistent bleeding despite benign biopsy
- Focal thickening/polyps, intracavitary lesion/malignancy

7.3.11 **Management overview**

- Routine surveillance for asymptomatic women using MHT or tamoxifen is not recommended due to low specificity & low PPV.
- Individualized management after risk stratification in asymptomatic women with an incidental finding of an increased endometrial thickness, postmenopausal ET ≥11mm.
- A blind endometrial biopsy that produces an "insufficient sample" can be considered as normal provided the biopsy device was inserted more than 6 cm beyond the cervical canal, individualize-risk factors & USG findings.

7.3.12 **Unscheduled bleeding with MHT in the absence of pathology**

- Exclude poor compliance, drug interactions, malabsorption
- Change dose, type of preparation or regimen
- Switch to non-oral MHT, LNG-IUS, topical estrogen, Stop MHT
- Offer surgery in refractory cases

7.3.13 **Tamoxifen:** Hysteroscopy guided biopsy preferred

7.3.14 **Atrophic endometritis:**

- Topical estrogen cream
- Antibiotics

7.3.15 **Hyperplasia/Malignancy:** Biopsy and treat with multidisciplinary team

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