



## CATEGORY: CLINICAL GUIDANCE

# Managing menopausal symptoms

This statement has been developed and reviewed by the Women's Health Committee and approved by the RANZCOG Board and Council.

RANZCOG acknowledges the contribution of the Australasian Menopause Society (AMS) in the compilation and continuous review of this statement.

A list of Women's Health Committee Members can be found in [Appendix A](#).

**Disclaimer** This information is intended to provide general advice to practitioners. This information should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The document has been prepared having regard to general circumstances.

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**Objective:** To provide advice on the management of menopausal symptoms.

**Target audience:** All health practitioners providing care for women, and patients.

**Values:** The evidence was reviewed by the Women's Health Committee (RANZCOG) and applied to local factors relating to Australia and New Zealand.

**Background:** This statement was first developed by Women's Health Committee in March 1995 and most recently in September 2020.

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## 1. Plain language summary

The Menopause is a normal reproductive stage in which egg production and menstrual periods stop permanently. Menopause typically happens in the early 50s but may occur earlier in certain populations.<sup>1</sup> Menopause before age 45 is regarded as “early” and before age 40 as “premature”.

Most women (around 80%) experience symptoms at menopause, most commonly hot flushes and/or night sweats and vaginal dryness. These usually do not need medical treatment but around 25% of women have severe and/or prolonged symptoms that may require medical intervention. For those who request treatment, drug free, non-hormonal and hormonal treatments are available.

## 2. Summary of Recommendations

Recommendation 1	Grade
Women approaching menopause should be offered information and advice about normal menopausal changes and symptoms and, if required, individualised discussion of management options for troublesome symptoms.	Consensus-based recommendation
Recommendation 2	Grade
This consultation is an opportunity for a routine health assessment, education and primary prevention general health and wellbeing including cardiovascular, bone and mental health. Current national breast and cervical screening guidelines should be followed. Bone density should be measured using DXA in those at increased risk of osteoporosis and fracture. Assessment of cardiovascular risk should be guided by age and risk factors	Good Practice Point
Recommendation 3	Grade
Women with a history of affective disorders and those with premature/ surgical menopause or following a cancer diagnosis may be at greater risk of developing anxiety and or depressive disorders during menopause. Consider mental health referral in those with symptoms of mood disorder.	Evidence -based recommendation Reference <sup>6</sup>
Recommendation 4	Grade
Women seeking relief from menopausal symptoms first should also be offered advice on lifestyle changes including stress reduction, regular exercise, optimal weight management, appropriate diet and avoidance of smoking. Excessive alcohol and caffeine intake should also be addressed.	Consensus-based recommendation Reference <sup>5</sup>
Recommendation 5	Grade
The most common indication for the use of MHT is the alleviation of troublesome menopausal vasomotor symptoms.	Consensus-based recommendation

Recommendation 6	Grade
Women with premature (less than 40 years) or early (less than 45-years) menopause should be offered MHT at least until aged 50 years unless otherwise contraindicated. <sup>5</sup>	Evidence-based recommendation Grade B
Recommendation 7	Grade
Commencement of MHT after the age of 60 is generally not recommended as benefits are less likely to outweigh risks.	Consensus-based recommendation Reference <sup>10</sup>
Recommendation 8	Grade
MHT should be considered for symptomatic women who have reduced bone density but have not sustained a fracture <sup>5</sup> .	Evidence-based recommendation Grade A
Recommendation 9	Grade
Oral MHT is contraindicated in women with previous a personal history of venous thromboembolism (VTE). <sup>5</sup>	Evidence-based recommendation Grade A
Recommendation 10	Grade
MHT should not be used for the primary prevention of CVD. <sup>5</sup>	Evidence-based recommendation Grade A
Recommendation 11	Grade
In women within 10 years of the menopause MHT does not increase the risk of coronary heart disease. <sup>5</sup>	Evidence-based recommendation Grade A
Recommendation 12	Grade
MHT should be avoided in women with a personal history of breast cancer	Consensus-based recommendation
Recommendation 13	Grade
Due to the increasing risk of breast cancer with duration of MHT, annual review of use is recommended. Continuation beyond 5-7 years should be based on an individual woman's needs with regards to the benefits and risks of continued MHT. <sup>5</sup>	Consensus -based recommendation
Recommendation 14	Grade
Oestrogen only therapy is appropriate for women who have undergone hysterectomy.	Evidence-based recommendation Grade A

Recommendation 15	Grade
Oestrogen plus progestogen should be used in women with an intact uterus	Evidence-based recommendation Grade A
Recommendation 16	Grade
The dose and duration of therapy should be consistent with treatment goals. The need for ongoing MHT should be reviewed regularly.	Consensus-based recommendation
Recommendation 17	Grade
For women with vaginal symptoms only, local vaginal oestrogen is the most suitable therapy. <sup>28</sup>	Consensus-based recommendation
Recommendation 18	Grade
Short term (1-2 years) use of vaginal oestrogen appears to be safe, though long-term data are lacking. Women using this therapy should be advised to consider intermittent withdrawal to review the need for ongoing therapy	Evidence-based recommendation Grade B
Recommendation 19	Grade
Use of topical vaginal oestrogen in women with a uterus does not require concomitant progestin use.	Consensus-based recommendation
Recommendation 20	Grade
Review use of MHT after 6 months, with regular subsequent reviews to reassess the balance of risks and benefits for the individual.	Consensus-based recommendation
Recommendation 21	Grade
Tibolone should only be used in women >12 months since menopause as it may cause irregular bleeding in younger women.	Consensus-based recommendation
Recommendation 22	Grade
Bioidentical hormonal therapies are not recommended as composition is not standardized, and efficacy and safety data is lacking.	Evidence-based recommendation Grade B
Recommendation 23	Grade
Paroxetine and fluoxetine should not be used in women taking tamoxifen as it may interfere with tamoxifen metabolism. <sup>40</sup>	Evidence-based recommendation Grade A

## 3. Overview

### 3.1 Menopause transition

RANZCOG fellows, members, diplomates and trainees should be confident discussing menopause with patients, providing information and access to evidence-based treatments.

The menopause is the final menstrual period. The “perimenopause” or “menopause transition” is the time from the onset of menstrual cycle changes until one year after the final menstrual period. A woman is postmenopausal 12-months after her final menstrual period. Timing of menopause can be difficult to determine following hysterectomy, endometrial ablation or in women using hormonal contraception. The early menopause transition is marked by a persistent difference of at least 7 days in length of consecutive cycles. The late menopause transition is marked by periods of amenorrhoea of 60-days or more, frequent anovulation and the onset of perimenopausal symptoms.<sup>2</sup> The menopause transition commonly starts around 47-years and the average age of natural menopause is 51-years. Previous hysterectomy and smoking are associated with earlier age at menopause.

The diagnosis of menopause is clinical, based on cessation of menstruation for a period of 12 months. For younger women or if the diagnosis is uncertain, elevated gonadotrophins (FSH) and a low oestradiol on 2 occasions can confirm menopause. AMH is not currently recommended to predict or diagnose menopause.

Most women do not require medical treatment for menopausal symptoms. From the age of 45 years (or earlier as appropriate) women should be offered information and advice about normal menopausal changes and symptoms and individualised discussion of management options for troublesome symptoms. This consultation should also be an opportunity for an overall health assessment and education about primary prevention for cardiovascular disease and osteoporosis, for example. Current national breast and

Recommendations 1	Grade
Women approaching menopause should be offered information and advice about normal menopausal changes and symptoms and, if required, individualised discussion of management options for troublesome symptoms.	Consensus-based recommendation
Recommendations 2	Grade
This consultation is an opportunity for a routine health assessment, education and primary prevention general health and wellbeing including cardiovascular, bone and mental health.	Consensus-based recommendation
Current national breast and cervical screening guidelines should be followed.	
Bone density should be measured using DXA in those at increased risk of osteoporosis and fracture.	

<https://www.osteoporosis.org.au/sites/default/files/files/RACGP%20Osteoporosis%20Summary%20Guideline%204428%20Nov%202017.pdf>

Assessment of cardiovascular risk should be guided by age and risk factors  
<https://www.heartfoundation.org.au/health-professional-tools/cvd-risk-calculator>

[http://www.sld.cu/galerias/pdf/servicios/hta/ebm\\_cardio\\_new\\_zeland.pdf](http://www.sld.cu/galerias/pdf/servicios/hta/ebm_cardio_new_zeland.pdf)

cervical screening guidelines should be followed.

Troublesome vasomotor symptoms (VMS) are the most common reason for women to seek advice and treatment during the menopause transition. Symptoms commonly start during the menopause transition with an average duration of 4-5 years. In around 10% of women symptoms may persist for more than a decade.<sup>3,4</sup> Vasomotor symptoms may affect quality of life and mood. Genitourinary symptoms may affect sexual activity or cause discomfort with daily activities. Joint symptoms may be more common in Asian women.<sup>1,5</sup>

The risk of osteoporosis increases after menopause. Fracture risk can be calculated using an online tool such as FRAX (<http://www.shef.ac.uk/FRAX>). Bone density can be measured in those at increased fracture risk using Dual X-ray Absorptiometry (DXA).

Symptoms of anxiety and depression are common in women and may be increased during the menopause transition, particularly in those with chronic sleep disturbance due to vasomotor symptoms. Menopause, due to life changes and aging, may be a time of vulnerability for the development of clinical anxiety and or depressive disorders. Women with a history of affective disorders and those with premature/early or iatrogenic menopause or following a cancer diagnosis may be at greater risk. Consider education, support and/or mental health referral in those at risk or with symptoms of a mood disorder.<sup>6</sup>

Recommendation 3	Grade
Women with a history of affective disorders and those with premature/surgical menopause or following a cancer diagnosis may be at greater risk of developing anxiety and or depressive disorders during menopause. Consider mental health referral in those with symptoms of mood disorder.	Evidence -based recommendation  Reference <sup>6</sup>

### 3.2 Management of troublesome menopausal symptoms

Management options for troublesome menopausal symptoms include non-pharmacological, non-hormonal and hormonal treatments. Menopausal hormonal therapy (MHT) is effective for vasomotor symptoms, but for some women it is unsuitable (due to preference or contraindications such as venous thromboembolism and hormone receptor positive cancers) and non-pharmacological or non-hormonal treatments can be considered.<sup>7</sup>

Quality of life issues should be discussed and assessed together with the risks of developing osteoporosis, cardiovascular disease, thromboembolism, and dementia associated with aging often coinciding with the menopause.

Lifestyle factors should be addressed and focused on as part of primary prevention and education including weight bearing exercise, calcium/ vitamin D intake, avoidance of smoking, excessive alcohol and caffeine intake, optimal weight maintenance and reduction of stress.

Sexual counselling should be considered for the woman, either on her own or with her partner.

Recommendation 4	Grade
Women seeking relief from menopausal symptoms should also be offered advice on lifestyle changes including stress reduction, regular exercise, optimal weight management, appropriate diet and avoidance of smoking. Excessive alcohol and caffeine intake should also be addressed.	Consensus-based recommendation  Reference <sup>5</sup>

## 4. Menopausal Hormone Therapy (MHT)

### 4.1 Indications and benefits

The principal indication for MHT is the relief of troublesome VMS impacting on quality of life. MHT is the most effective treatment for vasomotor symptoms and urogenital atrophy.<sup>5,8</sup>

Other menopausal symptoms which may improve with oestrogen include sexual dysfunction, sleep disturbance, mood swings and joint or muscle pains. However, treatment of low mood and libido is not a primary indication for MHT.

The decision to start and to continue MHT will depend on the nature and severity of menopausal symptoms, their impact on function and the individual health profile of the woman. Dose is generally titrated to symptom relief and side effects, but most clinical guidelines advise starting with low dose therapy.<sup>5</sup>

There are no fixed guidelines on duration. Whilst VMS may persist in around 40% of women age 60-65<sup>4,9</sup>, the risks of treatment may increase with longer duration of use. Annual follow up is recommended, to review general health status and need for continued MHT.

Starting MHT over the age of 60, or more than 10 years beyond menopause, is generally not recommended although, in the presence of persistent troublesome symptoms, continuation of existing therapy can be considered.

Young women experiencing menopause may have more severe symptoms and sexual dysfunction may be a greater concern. For women with premature ovarian insufficiency (age 40) or early menopause (< age 45) current guidelines recommend using MHT until the normal menopausal age (i.e. approximately 50 years of age).<sup>5</sup> Continued use beyond this time should be based on the same risk-benefit assessments at regular review as for other post-menopausal women.

Recommendation 5	Grade
The most common indication for the use of MHT is the alleviation of troublesome menopausal vasomotor symptoms.	Consensus-based recommendation



Recommendation 6	Grade
Women with premature (less than 40 years) or early (less than 45-years) menopause should be offered MHT at least until aged 50 years unless otherwise contraindicated. <sup>5</sup>	Evidence-based recommendation  Grade B
Recommendation 7	Grade
Commencement of MHT after the age of 60 is generally not recommended as benefits are less likely to outweigh risks.	Consensus-based recommendation  Reference <sup>10</sup>

MHT increases bone density and reduces fracture risk.<sup>5</sup> However, due to the remainder of the risk-benefit profile, prevention of osteoporosis or fracture is not a primary indication for MHT use. It may be used in asymptomatic women for whom other treatments are considered inappropriate. MHT should be considered for women with menopausal symptoms who have reduced bone density but have not sustained a fracture.

Recommendation 8	Grade
MHT should be considered for symptomatic women who have reduced bone density but have not sustained a fracture.	Evidence-based recommendation  Grade A

## 4.2 MHT Safety

A wide range of MHT products exist, with several different routes of administration, potentially all with different risks and benefits.<sup>5</sup> The safety of MHT depends on individual risk, dose and duration of MHT use and whether a progestogen is included. MHT appears generally safe if used within 10 years of natural menopause, although this may increase breast cancer risk.<sup>11</sup> Breast cancer risk appears greater with combined MHT compared to oestrogen alone, and greater exposure to progestogen (continuous vs intermittent) may lead to greater breast cancer risk. Whilst progestogens are likely to vary in their risk for breast cancer, there is no strong evidence that micronized (“natural”) progesterone is safer for the breast than other progestogens.<sup>11</sup>

Large randomized controlled trials of MHT in older postmenopausal women (average age 63) indicate that around 7 years of either combined or oestrogen-alone MHT does not increase all-cause, cancer specific or cardiovascular mortality up to 18 years later.<sup>12</sup> The long-term health consequences of MHT in younger postmenopausal women taking MHT are less well defined. Whilst some studies have suggested that MHT around the age of natural menopause may confer

some cardiovascular benefits this has not been confirmed in large RCT and the indication for MHT remains as the treatment of troublesome symptoms.<sup>13</sup>

#### 4.2.1 MHT and thromboembolic disease

Combined oral oestrogen plus progestin increases risk of VTE approximately 2 fold.<sup>14</sup> Oral oestrogen also increases VTE risk.<sup>14,15</sup> Risk increases with age and the presence of other risk factors including the hormone dose, obesity, smoking, immobility, thrombophilia and previous VTE. Women with prior VTE have been shown to have about 10% incidence of recurrent VTE with MHT, occurring within the first year of treatment.<sup>16</sup> In the absence of a personal or family history, screening for thrombophilias is not indicated before starting MHT.<sup>5</sup>

Compared with oral MHT, transdermal MHT does not appear to increase VTE risk in women at low risk for this condition.<sup>15</sup> A retrospective cohort study of post-menopausal women with first VTE event noted no increase in recurrence rates among women exposed to transdermal MHT but higher recurrence in the small group of women taking oral MHT.<sup>17</sup>

Recommendation 9	Grade
Oral MHT is contraindicated in women with a personal history of venous thromboembolism (VTE). <sup>5</sup>	Evidence-based recommendation  Grade A

#### 4.2.2 MHT and stroke risk

An increased risk of stroke has been reported amongst women over the age of 60 or >10 years from the menopause using either oral oestrogen or combined therapy. The increased risk is confined to ischaemic stroke and is probably related to thromboembolic risk. A large observational study found that whilst oral oestrogen and high doses of transdermal therapy increased stroke risk, no increase was seen when transdermal doses of 50ug or less were used.<sup>18</sup>

#### 4.2.3 MHT and cardiovascular disease

The relationship between MHT and cardiovascular disease is complicated by age and time since the menopause. In the follow up of The Women's Health Initiative RCT<sup>14</sup> Coronary Heart Disease was not significantly different during the intervention or post intervention phase for either estrogen only or combined therapy, compared with placebo. When stratified for women aged 50-59 in cumulative follow up, the risk was significantly reduced for users of estrogen only therapy (HR 0.65, 95%CI 0.44-0.96) and not increased for users of combined MHT. A recent systematic review<sup>13</sup> concluded that, overall, MHT conferred no protective effect on all-cause mortality, cardiovascular death, non-fatal infarction, angina or revascularisation but did increase risk of stroke and VTE. However, in women who started MHT less than 10 years after the menopause

there was lower mortality (RR0.70, 95%CI 0.52-0.95) and a lower incidence of coronary heart disease. There was no evidence of increased risk of stroke in this group. These findings are supportive of the 'window of opportunity' hypothesis that initiation of MHT in women within 10 years of their last period is associated with maximum benefit and minimal risk.

Recommendation 10	Grade
MHT should not be used for the primary prevention of CVD. <sup>5</sup>	Evidence-based recommendation  Grade A
Recommendation 11	Grade
In women within 10 years of the menopause MHT does not increase the risk of coronary heart disease. <sup>5</sup>	Evidence-based recommendation  Grade A

#### 4.2.4 MHT and breast cancer risk

MHT increases breast density and combined oestrogen-progestogen increases the risk of breast cancer.<sup>20</sup> The use of daily progesterone appears to increase risk above cyclic progesterone use and risk increases with duration of use.<sup>11</sup> Whether 5 years of combined MHT use is safe for the breast is uncertain, and breast cancer risk may persist after discontinuation of MHT.<sup>11,19</sup>

It is uncertain whether oestrogen alone increases breast cancer risk. Large RCT's suggest no increase in risk but observational studies indicate that oestrogen alone may increase breast cancer risk but to a lesser extent than combined MHT.<sup>11,20</sup>

The additional risk attributable to MHT is similar to the risks associated with sedentary lifestyle, obesity and alcohol consumption.<sup>10</sup>

MHT should be avoided after breast cancer.<sup>10</sup> For women at high inherited risk of breast cancer who do not have a personal history of breast cancer, MHT may be safe but data are limited.

Recommendation 12	Grade
MHT should be avoided in women with a personal history of breast cancer	Consensus-based recommendation

Recommendation 13	Grade
Due to the increasing risk of breast cancer with duration of MHT, annual review of use is recommended. Continuation beyond 5-7 years should be based on an individual woman's needs with regards to the benefits and risks of continued MHT. <sup>5</sup>	Consensus -based recommendation

#### 4.2.5 MHT and endometrial cancer risk

In women who have an intact uterus, unopposed oestrogen increases the risk of endometrial hyperplasia and cancer. Combined continuous MHT reduces the risk of endometrial cancer compared to untreated women.<sup>14</sup> Sequential MHT confers a slight increase risk of endometrial cancer.<sup>21</sup>

#### 4.2.6 MHT and ovarian cancer risk

A large meta-analysis of observational studies has reported an increased risk of ovarian cancer for users of MHT.<sup>22</sup> The increased risk was confined to serous and endometrioid subtypes whilst there was a reduction in risk of clear cell and mucinous subtypes. The absolute increase in risk was 2.4 per 10,000 women per year. The clinical significance of this is uncertain.<sup>23</sup> The only large randomised trial<sup>24</sup> examining MHT and ovarian cancer risk found no increase after 5 years of therapy, though was insufficiently powered for this rare outcome for the results to be definitive.

#### 4.2.7 MHT and gallbladder disease

Large RCT's have shown an increased risk of cholecystitis with oral MHT use amounting to around 12 extra cases per 1000 women per 5 years.<sup>25,26</sup>

#### 4.2.8 Other considerations prior to commencing MHT

MHT should not be commenced in women with undiagnosed vaginal bleeding.

Combined MHT may be associated with unscheduled bleeding during the first six months of therapy. Persistent, or new onset, bleeding beyond that time requires investigation.

In women with abnormal liver function tests transdermal therapy should be preferred.

Migraine is not a contraindication to MHT use however low dose transdermal therapy may be preferable.

### 4.3 Prescribing MHT

Simple clinical guidance, designed to be used in conjunction with more detailed guidelines may be obtained from The Global Consensus Statement on MHT use.<sup>10</sup>

The Practitioner's tool kit,<sup>27</sup> endorsed by RANZCOG, provides simple, algorithm-based steps for MHT use.

Common side effects of MHT include nausea, headache and breast tenderness. Initiating therapy with low doses should minimise these side effects whilst transdermal therapy is also less likely to induce nausea.

#### 4.3.1 Perimenopause

The combined oral contraceptive pill provides contraception, cycle control, relief from VMS and other symptoms. It will also prevent bone loss. Each woman's risks must be assessed, including smoking status, blood pressure, lipid profile and VTE risk. Eliminating placebo tablets can prevent VMS developing in the pill free week.

The levonorgestrel releasing intrauterine system (LNG-IUS) provides contraception and reduces uterine bleeding. LNG-IUS can provide endometrial protection from systemic oestrogen.

Cyclical (sequential) MHT may be initiated during the peri-menopause for alleviation of VMS however it is not contraceptive and will not regulate menstrual cycles.

#### 4.3.2 Postmenopause

For post-menopausal women treatment goals are alleviation of troublesome menopausal symptoms and improvement in quality of life. For women with an intact uterus MHT may be prescribed as oestrogen plus a progestogen for 14 days per month (cyclical therapy) or every day (continuous combined therapy). Cyclical therapy results in scheduled progestogen withdrawal bleeds. Continuous combined therapy results in amenorrhoea in 90% of women after 12 months although spotting and breakthrough is common in the first 3-4 months of therapy.

#### Systemic oestrogen

Oral oestrogen is available as oral conjugated oestrogens, micronised 17B oestradiol, oestradiol valerate or oestrone sulphate. Transdermal oestradiol patches, gel or implants may also be used for systemic MHT.

#### Topical vaginal oestrogen

Local vaginal therapy is preferred for women with isolated GU symptoms of menopause. Treatment is available in the form of pessary, tablet, cream and ring, with no significant differences between these formulations noted for effectiveness or development of endometrial hyperplasia.<sup>28</sup> Data on safety is primarily based on short-term trials, however for use over 1-2 years, there has been no evidence of an associated increase in risk of endometrial hyperplasia or cancer, DVT, breast cancer or cardiovascular disease.<sup>29,30,31</sup> Use of topical vaginal oestrogen therapy does not require additional use of a progestin in women with a uterus.

#### Progestogens

Progestogen therapy is required for systemic MHT in all women with an intact uterus and may be cyclical or continuous. Progestogens include micronized progesterone and synthetic progestins. It is uncertain whether micronised progesterone is safer than synthetic progestogen.<sup>32</sup> Progestogens are usually taken orally in a fixed dose combination with oestrogen or separately. Fixed dose combined transdermal patches are also available and the LNG-IUS may also be used for endometrial protection.

Recommendation 14	Grade
Oestrogen only therapy is appropriate for women who have undergone hysterectomy.	Evidence-based recommendation Grade A
Recommendation 15	Grade
Oestrogen plus progestogen should be used in women with an intact uterus	Evidence-based recommendation Grade A
Recommendation 16	Grade
The dose and duration of therapy should be consistent with treatment goals. The need for ongoing MHT should be reviewed regularly.	Consensus-based recommendation
Recommendation 17	Grade
For women with vaginal symptoms only, local vaginal oestrogen is the most suitable therapy. <sup>28</sup>	Consensus-based recommendation
Recommendation 18	Grade
Short term (1-2 years) use of vaginal oestrogen appears to be safe, though long-term data are lacking. Women using this therapy should be advised to consider intermittent withdrawal to review the need for ongoing therapy.	Evidence-based recommendation Grade B
Recommendation 19	Grade
Use of topical vaginal oestrogen in women with a uterus does not require concomitant progestin use.	Consensus-based recommendation

#### 4.3.3 Continuing or ceasing MHT

All women using MHT should be reviewed after 6 months therapy. This should include a general health check, a breast check and a mammogram every two years. Bone densitometry should be performed where indicated<sup>27</sup> and any unexpected vaginal bleeding after 6 months therapy requires appropriate investigation.

The risks of MHT may be related to duration of MHT use - for example, the risk of venous thromboembolism is greatest in the first year of use, but the risk of breast cancer increases with duration of use.

The need for ongoing MHT should be reviewed regularly. Base the decision on whether to advise continuation of MHT on symptoms and ongoing risks and benefits. There is no set minimum or maximum duration of therapy, though most guidelines recommend use for up to four to five years. Cessation of MHT may lead to resurgent symptoms in around 50% of women, with no clear evidence on the optimum method of discontinuing HRT.

Recommendation 20	Grade
Review use of MHT after 6 months, with regular subsequent reviews to reassess the balance of risks and benefits for the individual.	Consensus-based recommendation

## 4.4 Other hormones

### 4.4.1 Testosterone therapy

Testosterone therapy may be beneficial for postmenopausal women with hypoactive sexual desire disorders. This diagnosis requires a full assessment. Testosterone should not be routinely added to MHT in the treatment of menopausal symptoms.<sup>33</sup>

### 4.4.2 Tibolone

Tibolone, a synthetic steroid with oestrogenic, progestogenic and weak androgenic effects, is effective for vasomotor and urogenital symptoms in post-menopausal women.<sup>10,34</sup> It is not recommended in peri-menopausal women due to the potential for irregular bleeding. The relative efficacy of Tibolone compared to MHT is not well established.<sup>10</sup> In randomised trials, Tibolone has been shown to alleviate VMS, improve bone density and reduce fracture risk,<sup>35</sup> to have a modest effect on some domains of female sexual function<sup>34</sup> and to stimulate breasts less than combined MHT. Tibolone does not increase the risk of endometrial hyperplasia or cancer,<sup>35</sup> and is also associated with less bleeding in the first 3 months of treatment.<sup>36</sup> Tibolone increases the risk of breast cancer recurrence and increases risk of stroke in women >65 years.<sup>34,35</sup>

Recommendation 21	Grade
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Tibolone should only be used in women >12 months since menopause as it may cause irregular bleeding in younger women.	Consensus-based recommendation
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#### 4.4.3 Bioidentical hormones

The safety and efficacy of compounded bioidentical hormonal therapies is not established, and the composition of treatments is not standardised.<sup>37</sup> These drugs are generally not regulated by the Therapeutic Goods, Drug or equivalent administrations so manufacturing quality and dosage cannot be ensured. Use cannot be recommended. There is insufficient evidence to recommend the use of compounded progesterone creams.

Recommendation 22	Grade
Bioidentical hormonal therapies are not recommended as composition is not standardised, and efficacy and safety data is lacking.	Evidence-based recommendation  Grade B

## 5. Nonhormonal therapies

Several non-pharmacological and non-hormonal treatments are effective for VMS. There are few effective non-hormonal treatments for GU symptoms.

### 5.1 Non-hormonal therapies for VMS

Non-pharmacological treatments include hypnosis and cognitive behavior therapy.<sup>38</sup> Both have been shown to reduce troublesome VMS.<sup>7</sup> Yoga, exercise, diet, supplements or other lifestyle changes including weight loss have not been shown to reduce VMS.<sup>39</sup> However, these may confer other health benefits.

Over the counter complementary/ alternative medications, such as black cohosh and phytoestrogens, have not consistently been shown to be effective for VMS.<sup>7</sup>



Non-hormonal pharmacological medications shown to be superior to placebo in some randomised controlled trials include SSRIs (paroxetine, citalopram and escitalopram), SNRIs (venlafaxine, desvenlafaxine) and centrally acting medications including gabapentin, pregabalin and clonidine.<sup>5,39</sup> Most trials are short term only and longer-term data is lacking. Paroxetine and fluoxetine may interfere with tamoxifen metabolism.<sup>40</sup>

Recommendation 23	Grade
Paroxetine and fluoxetine should not be used in women taking tamoxifen as it may interfere with tamoxifen metabolism. <sup>40</sup>	Evidence-based recommendation  Grade A

## 5.2 Non-hormonal therapies for vaginal dryness

### 5.2.1 Lubricants and moisturisers

There is little evidence to support the effectiveness of vaginal moisturisers and lubricants.<sup>41</sup>

A randomised controlled trial of water- and silicone- based lubricants found that the silicone-based lubricant was more effective at reducing pain during sexual activity in patients with breast cancer.<sup>42</sup> A pilot study of olive oil (as a lubricant), vaginal moisturiser and pelvic floor muscle relaxation significantly improved dyspareunia, sexual function and quality of life after breast cancer.<sup>43</sup>

### 5.2.2 Vaginal lidocaine

Topical vulvar lidocaine (4%) applied for 3 minutes prior to penetration reduces pain during intercourse after breast cancer.<sup>44</sup>

### 5.2.3 Vaginal Laser

There are many publications about the use of fractionated CO<sub>2</sub> laser for treatment of menopausal vulvo-vaginal symptoms. Early case series have suggested that the treatment may improve vaginal dryness and dyspareunia, with more recent studies evaluating its effect on urinary symptoms.<sup>45</sup> Most studies remain limited by design and small subject populations. The few RCT's comparing laser with MHT<sup>46,47,48</sup> generally show no significant difference in outcomes between these therapies. Long-term outcome data is still lacking, and some studies have had contradictory results with some data suggesting increased pain with intercourse<sup>48</sup>, although a recent review<sup>49</sup> suggested a very low risk of serious complications, such as vaginal burns. As a result, use of vaginal laser therapy outside of clinical trials is not currently recommended. However, in the future there may prove to be a role for it in women who cannot, or do not wish to, use MHT, or for whom MHT does not result in satisfactory response.

## 6. Management of menopausal symptoms after cancer

Management of menopausal symptoms after cancer should include information about induced menopause and possible symptoms as well as available treatments. Management then requires a holistic and multidisciplinary approach with individualised care.<sup>50</sup>

Systemic MHT provides symptom control and may be used after most cancers but should be avoided after breast cancer and after some other oestrogen-dependent cancers (see table).

Vaginal oestrogen is effective for vaginal dryness. Safety after breast cancer is uncertain but a recent review<sup>51</sup> of topical oestrogen use for 1-2 years in breast cancer survivors found no associated changes in breast density or bi rads breast cancer risk score. Lubricants may also help with pain with sexual activity.

Women who have had cancer may need additional support, education and counselling about menopausal symptoms. Counselling should include discussion of the uncertain risks and benefits of MHT after cancer depending on the cancer type.

When any therapy is considered, the woman's other treating doctors should be involved in the decision-making along with the woman to provide individualised multidisciplinary care. A woman may wish to have her partner and/or other support people involved in any education, counselling and decision making.

Annual review including mammography is recommended for women on MHT.

**Table 1: Gynaecological cancers and MHT recommendation**

Cancer Type	MHT use	Comments
Cervical SCC or adenocarcinoma	Acceptable <sup>52</sup>	Not considered hormonally responsive. No correlation between ER or PR status and survival. <sup>53,54</sup>
Endometrial Ca - Stage I & II	May be considered <sup>55</sup>	Limited data available suggests no additional harm
Endometrial Ca - Stage III & IV	Not recommended <sup>52,55</sup>	No data to inform use.
Uterine Sarcoma	Not recommended <sup>52,55</sup>	Some are ER and PR positive, and respond to anti-E therapy. No data to demonstrate safety of MHT use in women with ER/PR negative tumours.
Ovarian Ca - high grade serous, clear cell, mucinous	Acceptable <sup>52</sup>	Limited data suggests no harm with E therapy.

Ovarian Ca - low grade serous & endometrioid	Not recommended <sup>52,55</sup>	
Vulval & Vaginal Ca	Acceptable <sup>55</sup>	Not considered hormonally responsive.

**Table 2: Non-gynaecological cancers and MHT recommendation**

Cancer Type	MHT use	Comments
Breast Ca	Avoid MHT <sup>10,56</sup> Avoid Tibolone <sup>57</sup>	No consensus on use of vaginal oestrogens. Consult with breast surgeon or oncologist to optimise treatment options for individual patients.
Colorectal Ca	Acceptable <sup>58,59</sup>	
Lung Ca – ER positive	No consensus <sup>39</sup>	
Haematological Ca	Acceptable <sup>54</sup>	
Malignant melanoma	No consensus <sup>39</sup>	

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## Glossary of Terms

**Menopause:** The permanent cessation of menstruation. The definition is made retrospectively, 12 months after the final menstrual period.

**Premature Menopause:** Menopause before the age of 40.

**Early Menopause:** Menopause before the age of 45, but after the age of 40.

**Perimenopause:** The period of time immediately prior to the menopause (when the endocrinological, biological, and clinical features of approaching menopause commence) and the first year after menopause.

## Links to other related College Statements

Tamoxifen and the Endometrium (C-Gyn 12)

[https://ranzcof.edu.au/RANZCOG\\_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20Gynaecology/Tamoxifen-and-the-endometrium-\(C-Gyn-12\).pdf?ext=.pdf](https://ranzcof.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20Gynaecology/Tamoxifen-and-the-endometrium-(C-Gyn-12).pdf?ext=.pdf)

Consent and provision of information to patients in Australia regarding proposed treatment (C-Gen 02a)

[https://ranzcof.edu.au/RANZCOG\\_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Consent-and-provision-of-information-to-patients-in-Australia-\(C-Gen-2a\).pdf?ext=.pdf](https://ranzcof.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Consent-and-provision-of-information-to-patients-in-Australia-(C-Gen-2a).pdf?ext=.pdf)

Consent and provision of information to patients in New Zealand regarding proposed treatment (C-Gen 02b)

[https://ranzcof.edu.au/RANZCOG\\_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Consent-and-provision-of-information-NZ-\(C-Gen-2b\).pdf?ext=.pdf](https://ranzcof.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Consent-and-provision-of-information-NZ-(C-Gen-2b).pdf?ext=.pdf)

Evidence-based Medicine, Obstetrics and Gynaecology (C-Gen 15)

[https://www.ranzcof.edu.au/RANZCOG\\_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Evidence-based-medicine,-Obstetrics-and-Gynaecology-\(C-Gen-15\)-Review-March-2016.pdf?ext=.pdf](https://www.ranzcof.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Evidence-based-medicine,-Obstetrics-and-Gynaecology-(C-Gen-15)-Review-March-2016.pdf?ext=.pdf)

## Other useful links

National Breast Screening Programme (BreastScreen Australia)

<http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/breast-screening-1>

National Cervical Screening Programme (Australia)

<http://cancerscreening.gov.au/internet/screening/publishing.nsf/Content/cervical-screening-1>

National Breast Screening Programme (New Zealand)

[http://www.nsu.govt.nz/National Cervical Screening Programme \(New Zealand\)](http://www.nsu.govt.nz/National_Cervical_Screening_Programme_(New_Zealand))

<http://www.nsu.govt.nz/>



Australasian Menopause Society-Combined Menopausal Hormone Therapy (MHT)  
[https://www.menopause.org.au/index.php?option=com\\_content&view=article&id=267:combined-menopausal-hormone-therapy-mht](https://www.menopause.org.au/index.php?option=com_content&view=article&id=267:combined-menopausal-hormone-therapy-mht)

Cardiovascular Disease Risk Assessment(NZ)  
[https://www.health.govt.nz/system/files/documents/publications/cardiovascular-disease-risk-assessment-management-primary-care-feb18-v4\\_0.pdf](https://www.health.govt.nz/system/files/documents/publications/cardiovascular-disease-risk-assessment-management-primary-care-feb18-v4_0.pdf)

## Patient information

A range of RANZCOG Patient Information Pamphlets can be ordered via:  
<https://www.ranzcog.edu.au/Womens-Health/Patient-Information-Guides/Patient-Information-Pamphlets>

## Appendices

### Appendix A Women's Health Committee Membership

Name	Position on Committee
Professor Yee Leung	Chair and Board Member
Dr Gillian Gibson	Deputy Chair, Gynaecology
Dr Scott White	Deputy Chair, Obstetrics
Associate Professor Ian Pettigrew	Member and EAC Representative
Dr Kristy Milward	Member and Councillor
Dr Will Milford	Member and Councillor
Dr Frank O'Keeffe	Member and Councillor
Professor Sue Walker	Member
Dr Roy Watson	Member and Councillor
Dr Susan Fleming	Member and Councillor
Dr Sue Belgrave	Member and Councillor
Dr Marilyn Clarke	ATSI Representative
Associate Professor Kirsten Black	Member
Dr Thangeswaran Rudra	Member
Dr Nisha Khot	Member and SIMG Representative
Dr Judith Gardiner	Diplomate Representative
Dr Angela Brown	Midwifery Representative, Australia
Ms Adrienne Priday	Midwifery Representative, New Zealand
Ms Ann Jorgensen	Community Representative
Dr Rebecca Mackenzie-Proctor	Trainee Representative
Dr Leigh Duncan	Maori Representative
Prof Caroline De Costa	Co-opted member (ANZJOG member)
Dr Christine Sammartino	Observer

### Appendix B Contributing authors

The committee acknowledges the contribution of Dr Martha Hickey and Dr Rebecca Szabo to this statement.

### Appendix C Overview of the development and review process for this statement

#### *i. Steps in developing and updating this statement*

This statement was originally developed in March 1995 and was most recently reviewed re-written in September 2020. The Women's Health Committee carried out the following steps in reviewing this statement:

- Structured clinical questions were developed and agreed upon.
- An updated literature search to answer the clinical questions was undertaken.
- At the September 2020 committee meeting, the existing consensus-based recommendations were reviewed and updated (where appropriate) based on the available

body of evidence and clinical expertise. Recommendations were graded as set out below in Appendix B part ii)

ii. *Grading of recommendations*

Each recommendation in this College statement is given an overall grade as per the table below, based on the National Health and Medical Research Council (NHMRC) Levels of Evidence and Grades of Recommendations for Developers of Guidelines.<sup>17</sup> Where no robust evidence was available but there was sufficient consensus within the Women's Health Committee, consensus-based recommendations were developed or existing ones updated and are identifiable as such. Consensus-based recommendations were agreed to by the entire committee. Good Practice Notes are highlighted throughout and provide practical guidance to facilitate implementation. These were also developed through consensus of the entire committee.

Recommendation category		Description
Evidence-based	A	Body of evidence can be trusted to guide practice
	B	Body of evidence can be trusted to guide practice in most situations
	C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
	D	The body of evidence is weak and the recommendation must be applied with caution
Consensus-based		Recommendation based on clinical opinion and expertise as insufficient evidence available
Good Practice Note		Practical advice and information based on clinical opinion and expertise

#### Appendix D Full Disclaimer

This information is intended to provide general advice to practitioners, and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient.

This information has been prepared having regard to general circumstances. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual patient and the particular circumstances of each case.

This information has been prepared having regard to the information available at the time of its preparation, and each practitioner should have regard to relevant information, research or material which may have been published or become available subsequently.

Whilst the College endeavours to ensure that information is accurate and current at the time of preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available.