### Definition

**Menopause** is the absence of a spontaneous menstrual period for one year. The average age for the onset of menopause in American women is age 51. The age range is 45-55 (8% of American women enter menopause before age 40).

### Symptoms

- Change in menstrual pattern (oligomenorrhea, amenorrhea)
- Vasomotor symptoms (hot flashes)
- Insomnia/sleep disturbances
- Urinary tract and vaginal atrophy (dysuria, urinary frequency, dyspareunia)

### Diagnostic Evaluation

A diagnostic evaluation is an opportunity for physicians to provide and encourage a program of preventive healthcare.

**Diagnostic evaluation should include:**

- History
- Physical examination
- Lab and diagnostic tests
- Counseling

**Education should include:**

- Diet – Menopausal women should have a daily intake of 1200 to 1500 mg of calcium (diet plus supplement)
- Exercise – Recommend weight bearing physical activity 30 minutes, three times a week
- Smoking cessation – Smokers experience earlier menopause and increased risk of osteoporosis
- Control of hypertension, diabetes and lipids
- Breast health

### Menopause Counseling

Menopause counseling is a critical component of helping women make educated, well-informed decisions regarding what therapy, if any, is right for them. The decision to initially prescribe or to continue use of hormone therapy requires a thorough evaluation of the benefits and potential risks for each individual woman.

**Counseling may include some or all of the following steps:**

- Review the consequences of estrogen deficiency, including short-term and long-term health conditions
- Review on an ongoing basis the short-term and long-term risks and benefits of all treatment options
- Personalize discussions on the woman’s health, social history and family history
- Supplement discussions with patient education materials when applicable
- Consider the patient’s preferences, relative risk factors and key concerns when making a decision on treatment
- Schedule routine follow-ups for all patients who start any type of treatment
- Prescribe treatment regimen appropriate to each woman’s physical and psychosocial needs

### Hormone Therapy

#### Indications

- Reduce vasomotor symptoms
- Reduce symptoms of atrophy affecting urogenital tract

#### Contraindications

- Known or suspected pregnancy
- Known or suspected breast cancer
- Undiagnosed abnormal vaginal bleeding
- Active thrombophlebitis or thromboembolic disorders
- Active liver disease
- Chronic impaired liver function
- Active gallbladder disease
- Neuropathic vascular disease
- Heart disease

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Based on ACOG guidelines and ACOG’s response to the WHI Study (July 2002)

Oxford Reviewed: Q1 2001, Q1 2003, Q2 2003

Oxford Approved: Q1 2001, Q2 2003
Women who take systemic hormone therapy to reduce vasomotor symptoms should only take the lowest dose for the briefest time possible. Once a woman is asymptomatic, she should be counseled, at least on an annual basis, on the benefits and risks of long-term use as well as alternative treatments. Most women can discontinue use after one to three years. Alternative treatments should be discussed before and throughout duration of hormone therapy use. Other therapies, such as bisphosphonates and selective estrogen receptor modulators (SERMs), are available for reducing the risk of developing osteoporosis.

Use of vaginally applied topical estrogen in cream, tablet or ring forms may be an effective alternative to systemic use for the treatment of symptoms related to urogenital atrophy. These preparations produce lower circulating levels of estrogen than systemic forms, and have not been identified as offering the same cardiovascular and cancer risks as combined estrogen-progesterin systemic regimens.

Women who are on hormone therapy should have an annual physical examination, which should include, but not be limited to, blood pressure screening, pap smear, lipid profile, and mammography.

Although there are no definitive data to indicate how systemic hormone therapy should be discontinued, gradual tapering of use should be considered to reduce any adverse effects, such as vaginal bleeding and return of vasomotor symptoms.

### Potential Risks Associated with Hormone Replacement Therapy

Based on the findings of the Women’s Health Initiative Study, the following risks of combination estrogen/progesterin therapy are identified:

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Description</th>
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<tbody>
<tr>
<td>Breast Cancer</td>
<td>There is a cumulative increase in the risk of invasive breast cancer in women taking combined estrogen/progesterin therapy.</td>
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<tr>
<td>Pulmonary Embolism</td>
<td>Estrogen and progesterin combinations have been associated with a greater than two-fold increase in the risk of pulmonary embolism.</td>
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<tr>
<td>Stroke</td>
<td>There is an increase in the risk of stroke in women taking estrogen/progesterin combination therapy. The increased risk becomes apparent during the second year of use and it is cumulative over the duration of use.</td>
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<tr>
<td>Endometrial Cancer</td>
<td>Unopposed estrogen therapy (without progesterin) is associated with a 2-fold increase in the risk of endometrial cancer in women with an intact uterus. Clinical and epidemiological data suggest that the risk of endometrial cancer is not increased in women taking estrogen and progesterin.</td>
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<tr>
<td>Gallbladder Disease</td>
<td>Hormone therapy slightly increases a woman’s risk of cholecystitis/cholelithiasis.</td>
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<tr>
<td>Elevated Triglycerides</td>
<td>Oral forms of hormone therapy may increase serum triglyceride levels.</td>
</tr>
<tr>
<td>Cardiovascular Disease</td>
<td>Estrogen and progesterin combinations are associated with a small but statistically significant increase in the risk of cardiovascular events. This combination therapy does not appear to offer postmenopausal women protection against heart disease as previously thought.</td>
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</tbody>
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### Side Effects of Hormone Therapy

Side effects of hormone therapy may include headaches, bloating, breast tenderness, irritability, uterine bleeding, and/or depressive symptoms.
### Types of Oral Treatment Regimens

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<th>Dosage and preparation of estrogen and/or progestin should be individualized based on the patient’s risks and needs.</th>
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<tr>
<td><strong>Sequential 1</strong></td>
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<tr>
<td><strong>Sequential 2</strong></td>
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<tr>
<td><strong>Continuous</strong></td>
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</tbody>
</table>

**Estrogen-progestin combination** should be used for women with an intact uterus to protect against hyperplasia and/or carcinoma when hormone therapy is appropriate.

**Estrogen only** Estrogen is taken daily without the addition of a progestin. Estrogen alone is appropriate for women without a uterus. For women with a uterus, who do not tolerate progestin, estrogen-only treatment is an option as long as the patient is closely monitored with endometrial biopsy.

### Some commonly used estrogen preparations include:

- Oral conjugated estrogen .3mg - .625 mg
- Oral micronized estradiol .5mg - 1 mg
- Oral piperazine estrone sulfate .75 mg
- Transdermal estradiol .05 mg
- Oral esterified estrogen .3 mg
- Estradiol vaginal ring

**Progestin only** Progestin alone may be used in women with vasomotor symptoms and/or risk of osteoporosis who do not tolerate estrogen.

### Some commonly used progestin preparations include:

- Medroxyprogesterone acetate (Provera) 10-30 mg
- Norethindrone 1 -5 mg

**Estrogen-androgen** These preparations may be useful in the treatment of moderate to severe vasomotor symptoms in those patients not improved by estrogen alone. They may also be of benefit in patients with significant decrease in libido associated with menopause.

- Methyltestosterone 1.25-2.5 mg
- Methyl testosterone/Esterified estrogen 1.25 mg/2.5 mg (Estratest) or .625 mg/1.25 mg (Estratest HS)

Please note: The FDA is currently reviewing data regarding the efficacy of commercially available estrogen/androgen combinations. New recommendations regarding the use of these agents based on this assessment are likely to appear in the near future.

**Selective estrogen modulators** Raloxifene (Evista) is recommended for osteoporosis prevention. There is no evidence that it relieves other menopausal symptoms, and it may exacerbate symptoms of hot flashes in some women.

- Raloxifene hydrochloride 60 mg
### Bisphosphonates
Alendronate (Fosamax) and risedronate (Actonel) are approved for treatment and prevention of osteoporosis in postmenopausal women.

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<td>Alendronate sodium</td>
<td>10mg (daily dose); 70 mg (weekly dose)</td>
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<tr>
<td>Resedronate sodium</td>
<td>5 mg (daily dose); 35 mg (weekly dose)</td>
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### Preparation
There is no evidence of a general advantage of one form of estrogen over another. Estrogen is available in a variety of preparations, including pills, transdermal patch, vaginal tablets, vaginal ring, and vaginal cream.

We value your input on our guidelines. If you have any questions or comments, please e-mail sklesyk@oxfordhealth.com or write to:

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**48 Monroe Turnpike**  
**Trumbull, CT 06611**

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