**VASOMOTOR SYMPTOMS**

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<th>DEFINITION</th>
<th>Most perimenopausal and post-menopausal women experience vasomotor symptoms (hot flashes/flushes) and other estrogen deficiency/estrogen fluctuation problems, including mood swings, vaginal atrophy and sleep disturbances. Over half of postmenopausal women with hot flashes suffer moderate to severe symptoms, which disrupt their functionality and their quality of life. Other conditions (e.g., thyroid dysfunction, tuberculosis) that cause similar symptoms must be considered. There are many different therapeutic approaches to aid symptomatic women although the medical treatments recommended for premenopausal women may differ from those offered to post-menopausal women.</th>
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| SUBJECTIVE | Must include at least one of the following complaints: 1. Hot flashes  
   a. Note severity and frequency  
   b. For premenopausal women, note timing within cycle.  
2. Sleep disruption due to hot flashes.  
3. Mood changes due to sleep disturbances.  
Must exclude: Medical conditions that would preclude use of desired therapy. (See Attachment 1 for contraindications to post-menopausal hormone therapy). |
| OBJECTIVE | Must include: 1. Weight, BMI.  
2. BP. |
| LABORATORY | No routine labs needed; in women with clinical indications, consider TSH.  
Note: Measurement of FSH, LH, estradiol or other sex steroids is **not** indicated in either symptomatic perimenopausal women or in women known to be postmenopausal. |
| ASSESSMENT | Perimenopausal or post-menopausal woman with vasomotor symptoms. |
| PLAN | 1. Recommend lifestyle changes to promote long term health:  
   a. Weight control.  
   b. Exercise.  
   c. Smoking cessation.  
2. Advise lifestyle changes to reduce impacts of hot flashes:  
   a. Layered clothing.  
   b. Temperature and humidity control.  
   c. Avoidance of foods and activities that trigger hot flashes.  
   d. Use of personal fans, sprays, relaxation techniques.  
   e. Acupuncture has been shown to modestly reduce the number of hot flashes.  
3. Nonhormonal prescription therapies. Do not combine 2 of these therapies or one of these with hormonal therapies for vasomotor relief. If patient desires nonhormonal therapy, consider one of the following:  
   a. Low dose SSRIs (selective serotonin reuptake inhibitors): reduce number of hot flashes by 30-60%. Select one of the following:  
      1) Paroxetine (Paxil) 10-20mg or Paroxetine CR 12.5-25 mg orally once daily (**Do not stop abruptly, but taper when discontinuing. Be aware that Paxil changes metabolic clearance of tamoxifen.**)  
      2) Desvenlafaxine 100 mg orally daily.  
   b. SNRIs (selective serotonin-norepinephrine reuptake inhibitors): Venlafaxine (Effexor) 37.5 or 75 mg orally daily. Reduces number of hot flashes by 40-60%, depending upon dose.  
   c. Clonidine 0.05-0.1 mg transdermal patch per week. If patient has hypertension, consult with primary care provider before prescribing. Reduces number of hot flashes by about 30-40% but... |
is associated with orthostatic hypotension and dry month. Oral equivalent is not as effective and may have greater side effects.

d. Gabapentin (Neurontin) may be as effective as estrogen in reducing number of hot flashes and the intensity of those flashes. Refer to MD for prescribing.

4. Hormonal therapies.

a. Perimenopausal women who need contraception, offer one of the following:
   1) Low dose combined hormonal contraception: See protocol 2.5.1 Combination Hormonal Contraceptive Methods: Identification of Candidate, and Initial Start or Restart. Usually shortened hormone free interval or extended cycle formulations are preferred because women tend to become symptomatic during the hormone-free days.
   2) DMPA with or without postmenopausal estrogen therapy: See protocol 2.4.1 Systemic Progestin Only Contraceptive Methods: Identification of Candidate, for Initial Start or Restart protocol.

b. Postmenopausal women who have no absolute or strong relative contraindications to ET/HT (see Attachment I), may be considered for one of the following therapies:
   1) If patient has no uterus.
      a) Estrogen-only therapies preferred.
         (1) Start with the lowest dose of systemic therapy needed, e.g., 0.3mg CEE, 0.025mg E2 patch. Increase dose only if no improvement noted after 3-4 weeks of use. If symptom relief not adequate by 6-8 weeks, may need to increase dose.
         (2) Oral or transdermal options of post-menopausal estrogen therapy are available. Be guided by cost, patient preferences and current evidence about DVT risk. Transdermal estrogen preparations may be preferred over oral preparations in women who have:
            • Elevated triglycerides (if > 300, consult MD).
            • Inability to absorb orally administered estrogens.
            • Current gallbladder disease.
            • Hepatic dysfunction (chronically mildly elevated LFTs).
            • Current use of tobacco.
            • Current use of medications that cause rapid metabolism of estrogen.
            • Minor risk factors for thromboembolism (but patient is still a candidate).
         (3) If a woman has a history of breast tenderness, may ease into hormone therapy by starting with low doses and/or by giving Saturdays/Sundays off.
   2) If patient has an intact uterus, treatments vary upon her preferences for periodic bleeding as well as any medical contraindications (See Attachment 1).
      a) For a woman who desires scheduled periodic bleeding or may temporarily need it because of difficulty controlling spotting and bleeding while taking continuous combined hormonal therapy, offer one of the following:
         (1) An estrogen (oral, transdermal or cutaneous) every day and an oral, transdermal or vaginal source of progestin (minimum MPA (Provera) 5 mg equivalent) for 12-14 days each cycle.
         (2) Cyclic combination products (generally available with daily estrogen for 25 days with a progestin added for the last 12 days followed by hormone-free days).
      b) For a woman who desires to avoid scheduled bleeding, offer one of the following options:
         (1) A continuous combination post-menopausal hormone product.
         (2) An estrogen source and a progestin source without interruption.
         (3) Note: if the patient has had <13 month amenorrhea or is obese, consider administering 10 days of MPA (5-10 mg every day) to slough endometrial lining prior to initiating continuous combined HT to reduce subsequent spotting and bleeding on hormone therapy.
   3) Advise patient that estrogen and estrogen/progestin therapies generally reduce the frequency and severity of hot flashes by about 90%.
      a) Discuss each woman’s own personal risks and benefits of ET/HT.
      b) Inform patient that principle of therapy is to use the lowest dose needed for the shortest
### PLAN
(Continued)

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<td>c)</td>
<td>Remind patient that post-menopausal hormone therapy is not to be used for the prevention of cardiovascular disease, but that ET/HT does significantly reduce risk of osteoporosis and fracture.</td>
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<td>d)</td>
<td>Reassure patient that together you will reassess her need for therapy periodically, based not only on her assessment of a continuing need for treatment, but also your assessment of her risks and the availability of any new therapies at that time.</td>
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### PATIENT EDUCATION

1. Reinforce need for healthy lifestyles with weight bearing exercise, healthy diet, achieving and maintaining BMI< 25, smoking cessation, moderation in alcohol consumption, stress reduction and building an active social network
2. Recommend increase in calcium RDA to 1200 mg daily unless patient using hormonal therapies (RDA then remains 1000 mg per day). RDA for vitamin D is 600 IU daily.
3. Recommend weight bearing and aerobic exercise for cardiovascular health, osteoporosis prevention and reduction of vasomotor symptoms. Minimum requirements are 45 minutes of exercise 3 times a week.
4. Advise women to adhere to sensible, low fat balanced diet for weight control and appropriate weight distribution (waist/hip ratio).
5. Encourage routine health screening testing, including breast exams and mammography.
6. Advise women that on average vasomotor symptoms last about 2-3 years, but that some women have symptoms for decades. In general, the earlier symptoms develop, the longer they will last.
   a. Women who have late onset of vasomotor symptoms and those who have prolonged symptoms may be at higher risk for cardiovascular disease later in life.
7. For women using SSRIs and SNRIs for hot flashes
   a. Advise women that these drugs have been shown to reduce the frequency of hot flashes up to 50%, but do not affect the intensity of the flashes.
   b. Reassure patient that you are not prescribing these drugs to treat her for depression; the doses used for hot flash control are lower than those used for depression.
   c. Describe the side effects that may develop with use of the SSRI/SNRI drugs such as Paroxetine, Venlafaxine or Desvenlafaxine including insomnia, somnolence, dizziness, nausea, dry mouth, restless leg syndrome, increased blood pressure, numbness and decreased balance control.
   d. Remind Paroxetine users to taper the frequency of Paxil use over 2 weeks before stopping the drug. No cold turkey stops.
8. Women using or wanting to use over-the-counter (OTC) herbal or botanical products for vasomotor symptoms:
   a. Review the contents of those products with patient to assess if they present any drug-drug interactions with her current medications. Several of the herbal products can significantly alter metabolism of prescription drugs.
   b. If woman is having success with an OTC product and there are no dangerous drug-drug interactions, advise her to at least periodically reassess her need for continued use. Remind her that the safety of those products has not been adequately tested.
   c. If the patient is just considering use of an OTC herbal product, inform her that good scientific studies have shown that none of those products provides any more relief for her symptoms than sugar pills. Remind her that the safety of those products has not been adequately studied and the purity is not known.
9. For women initiating or continuing use of postmenopausal hormonal products:
   a. Describe the risks and benefits of HT in general and of the formulation she is using in particular. Note that for recently menopausal women, there is no increase in the risk of heart disease, lung cancer or breast cancer with short term use of these products.
   b. Review warning signs and symptoms of rare serious adverse effects including those for myocardial infarction, stroke, thrombosis, and cholelithiasis. Tell patient that if any of those develop, she should discontinue HT and seek emergency medical care.
   c. Explain possible side effects including breast tenderness, bloating, and changes in complexion, weight change and/or mood. For women with a uterus, vaginal spotting and bleeding are not
uncommon. Advise patient to RTC if any bothersome side effects develop/persist so her HT can be changed to minimize those problems.
d. Reassure patient that use of postmenopausal hormones will not cause her to gain additional weight.
e. Encourage consistent use. Inform patient that interrupting treatment can cause vaginal spotting or bleeding (if she has intact uterus).
f. Advise patient that vasomotor symptoms should be noticeably reduced in 3 to 4 weeks, but that the ultimate effect may not be seen for up to 6 weeks or more. Remind patient that the treatment will not completely eliminate all flashes, but should provide significant relief.
g. Advise her that if she still has vaginal dryness with use of systemic hormonal therapy, she may need local treatment for that problem.
h. Suggest that post-menopausal hormone users stop using their postmenopausal therapies 2-3 weeks prior to getting a mammogram in order to improve the ability of that mammogram to detect any early breast disease.
i. Warn women who want so-called bioidentical hormones that are not FDA-approved, that those products are not tested for safety or purity and that there are FDA-approved versions available for many of them.

REFER to MD/ER
1. Patient with absolute contraindications to HT who desires to use it.
2. Patient with strong relative contraindications requiring MD consult.
3. Patients with bothersome side effects.

REFERENCES
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**ATTACHMENT 1**

**Absolute contraindications to ET/HT**

1. History of myocardial infarction, coronary artery disease, arrhythmia, significant dyslipidemia.
2. History of significant adverse reaction to oral contraceptives or previous HT administration.
3. Active or past history of thromboembolism.
5. Undiagnosed, abnormal genital bleeding (until evaluated).

**Strong relative contraindications to ET/HT (Obtain MD consult)**

1. Hypertension.
2. Diabetes.
3. Renal failure or significant renal impairment.
4. Current or history of classic migraine headaches.
5. Current or history of endometriosis.
6. Gallbladder disease, known or suspected.
7. Carcinoma of the breast, known or suspected, current or past history.
8. Estrogen-dependent neoplasia, known or suspected, current or past history.
9. Impaired liver function disease.
10. BMI > 40.