

# The Female Patient®

## Pharmacologic Treatment Options for Menopausal Symptoms

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Recently, a roundtable symposium of leading health care professionals in women's health gathered to review and discuss pharmacologic treatment options for menopausal symptoms. They discussed patient assessment and dissected the selection of therapies for determining the optimal patient-centered treatment regimen.

### INTRODUCTION

The menopausal transition, or perimenopause, generally starts when women are in their mid-to-late 40s and proceeds until 12 months after their final menstrual period (menopause), usually 4 to 5 years later.<sup>1,2</sup> Perimenopause is associated with several somatic and psychological symptoms that affect a woman's quality of life (Table 1).

While some symptoms, such as vasomotor symptoms and vaginal dryness, appear to be purely physiological, others, such as difficulty concentrating and decreased sexual desires, have a more complex etiology that may

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be related to or a consequence of the physical symptoms. It has been difficult to distinguish whether symptoms such as anxiety, depression, and mood changes, which are often associated with the menopausal transition, are causally related to a decrease in ovarian hormone production, or to other life factors.<sup>1</sup>

Vasomotor symptoms, also known as hot flashes, hot flushes, and night sweats, are spontaneous sensations of warmth, generally around the face, neck, and chest.<sup>1</sup> Hot flashes are common and occur in an estimated 12% to 65% of North American women,<sup>3</sup> although the prevalence of such symptoms varies widely. They can be triggered by warm environments, hot foods or drinks, and anxiety or stress.

Urogenital issues, such as vaginal dryness, itching, irritation, and pain with intercourse (dyspareunia) are also associated with physiological responses to a decrease in estrogens and androgens.<sup>1</sup> The clinical signs of vulvovaginal atrophy include changes to the vaginal epithelium, which becomes thinner, drier, less elastic, and more easily irritated. The vaginal pH, typically 3.5 to 4.5 premenopausally, increases to >4.5 in most women after menopause.<sup>4</sup> The composition of vaginal flora may change, creating a more favorable environment for gram-negative pathogens and *E coli* in particular, predisposing the menopausal woman to urinary tract and vaginal infections. Symptoms such as urinary urgency, frequency, urethral discomfort, and stress incontinence may develop due to urogenital atrophy.<sup>5,6</sup> An estimated 10% to 50% of postmenopausal women are affected by vulvovaginal atrophy symptoms.<sup>5,7</sup>

"The term 'vaginal dryness' is vague and problematic, because it's like asking a woman if she has vaginal discharge. Everybody's going to tell you 'yes' depending on how you phrase it."

*Anne Moore, RNC, MSN, ARNP*

When assessing a menopausal woman, clinicians may have difficulty with vague or ubiquitous terms like vaginal dryness. Many women will answer yes when asked if they have vaginal dryness; thus, it is important for the clinician to further question whether the vaginal dryness is also causing irritation or pain with intercourse, burning upon urination, or other symptoms. Examination of the vaginal walls for clinical signs, such as diminished rugosity (the typical

wrinkles that appear in the vaginal mucosa), will also help confirm the symptom and may guide treatment decisions. Vaginal dryness may occur at any time during the menopause transition and may progress as the woman ages and vaginal atrophy becomes more pronounced.

In addition to traditional menopausal symptoms, many women present with complaints of weight gain, decreased sexual desire, loss of concentration, and joint pain, which may or may not be related to menopause. Sleep disturbances, possibly due to hot flashes, are common among menopausal women, and may contribute to psychological symptoms such as anxiety, irritability, and depression.

**TABLE 1. Menopausal Symptoms**

<b>Vasomotor</b>	Hot flashes Night sweats or chills
<b>Sexual Health</b>	Genital dryness, pain, and/or burning Pain during sexual activity Decreased sexual desire Decreased sexual response Decreased sexual frequency
<b>Psychological</b>	Anxiety Irritability Depression Difficulty concentrating
<b>Other</b>	Sleep disturbances Fatigue Joint pain or stiffness Weight gain

Symptoms such as vaginal dryness, sleep disturbances, and mood changes contribute to concerns about sexual health as a woman ages.<sup>8</sup> The complex interplay of menopausal symptoms, psychological health, and relationship factors affect sexual quality of life. A partner's frequent use of male erectile dysfunction treatments may also affect a woman's sexual quality of life.

Diagnosis of sexual issues is critical; however, many clinicians do not initiate conversations about sexual health during routine post-menopausal visits. In addition, focusing the discussion on the woman's chief concern may be difficult when several vague complaints are mentioned. Assessment of menopausal symptoms can be facilitated with the assistance of a short questionnaire that provides the clinician with more information about specific problems and their impact on the woman's quality of life. One such instrument, The Menopause Impact Tool (Appendix I, [www.femalepatient.com](http://www.femalepatient.com)) can be given to women in the waiting room for completion prior to seeing their clinician to aid in conducting focused discussions on the woman's chief concerns. This assessment tool can also be given to patients at the conclusion of the annual well-woman visit to prepare for future discussions about specific problems. The last section of questions regarding attitudes toward hormone therapy (HT) can facilitate discussions on treatment options.

**CURRENT TRENDS IN HORMONE THERAPY**

Following the reporting of results from the Women's Health Initiative (WHI) study<sup>9,10</sup> and the depiction of those results by the media, scores of women abruptly discontinued HT amid concerns of serious health risks

associated with HT. Since the WHI results were originally reported, several reevaluations of the data have taken place and have shown that HT can be beneficial in suitable women.<sup>11,12</sup> To determine current attitudes about HT since the original publication of the WHI data, Birkhäuser et al surveyed 600 gynecologists, ObGyn specialists, and general practitioners from 6 countries, including the United States, to establish their attitudes and practices on HT use for treatment of menopausal symptoms.<sup>13</sup> Of the practitioners surveyed, 98% felt that a woman's quality of life was significantly affected by menopause. Additionally, 97% felt that the majority or all of their patients experienced positive benefits from HT, and 90% believed the benefits outweighed the risks of HT in suitable women. With these statistics in mind, the roundtable panelists provided their insights into patient and clinician perceptions of menopause and their expectations of menopause treatment.

Overall, the media is now playing a large role in how women perceive menopause and available treatment options. When news outlets provide only a brief commentary on a study, it can often lead to misconception and result in a burst of calls to clinicians for translation

**T**he patient's expectation is that I will take all of my knowledge and rational thinking about the issues and prescribe for them what I think would be effective, yet safe."

*Henry Hess, MD*

of what was reported. Popular mainstream TV characters also may portray menopausal events that precipitate patient-clinician interaction. Following an episode of the popular TV series *Sex in the City* in which the character Samantha experienced a hot flash and was shown profusely sweating while giving a presentation, Dr London's office received almost two dozen calls from women saying, "That's how I am at work." Clinicians need

to be cognizant of the reluctance of patients to voice their menopausal symptoms when they come in for routine visits. Clinicians should also have forthright discussions on information presented in the media, and accurately present both the pros and cons of therapy options for menopausal symptoms.<sup>14</sup>

Asking questions in a more systematic symptom-specific manner allows the clinician to understand how menopause is affecting the woman's quality of life. Many women are unaware of the genital and sexual problems associated with menopause, or are uncomfortable discussing these problems with their clinician.<sup>15,16</sup> Additionally, many clinicians may feel uncomfortable asking questions of a sexual nature, or may feel unprepared to answer them. As the awareness of sexual health increases, the need for clinicians and patients to have an open and honest conversation about sexual problems has come to the forefront. "We have to get doctors to be more aware, and to ask the sexual questions," says Dr Simon.

## Resources

### North American Menopause Society

[www.menopause.org/Consumers.aspx](http://www.menopause.org/Consumers.aspx)

### Mayo Clinic

[www.mayoclinic.com](http://www.mayoclinic.com)

### National Women's Health Information Center

[www.4women.gov](http://www.4women.gov)

### Women's Health Initiative

[www.WHI.org](http://www.WHI.org)

### US Food and Drug Administration

[www.fda.gov/womens/menopause](http://www.fda.gov/womens/menopause)

### WebMD

[www.webmd.com/menopause/](http://www.webmd.com/menopause/)

### Duramed Research

[www.copewithmenopause.com](http://www.copewithmenopause.com)

### Red Hot Mamas

[www.redhotmamas.org/](http://www.redhotmamas.org/)

### UpToDate for Patients

[www.uptodate.com/patients/index.html](http://www.uptodate.com/patients/index.html)

As women begin to experience symptoms during perimenopause (while still menstruating) as well as following their last period (menopause), many are using the Internet to gather information on menopause and the changes that may take place before, during, and thereafter. There are many credible Web sites that can help women learn about menopause and the available treatment options (Resources box, this page). Women may first seek alternative treatments such as vitamins, herbal supplements, and over-the-counter vaginal moisturizers and lubricants, to help them cope with their symptoms, as there is still fear that HT could be detrimental to long-term health. Many women find these therapies do not provide symptom relief, and instead search for a clinician who will take a "holistic approach" to helping them.

Women want relief from menopausal symptoms, but are increasingly seeking to participate in their treatment

decisions. They want to know what is available, how a particular treatment will affect them with their particular medical history, and the chances of developing cancer or other serious illnesses due to use of a particular therapeutic option. The clinician becomes a translator for what the person has seen on the Internet or has heard from their friends or through the media. "Though it is a negotiation, it also becomes an educational process for the patient," says Anne Moore, RNC, MSN, ARNP.

A woman's willingness to try HT is related to education—a process that may not be completed in one office visit. Clinicians need to work with the patient to determine what will work for her. Dr London tells his patients, "Nobody knows you better than you. You will tell me whether to go up or down. You will be guiding this and your symptoms will be guiding you because you're different than the next person."

Where will HT be in the next 5 years? The panelists agreed it will be centered around the patient and her wants: a positive self image, the ability to be sexy and have sex, and to sleep well. The means of attaining these goals may be oral or topical therapy, but the focus will be the patient and her specific needs.

## TREATMENT OPTIONS

There are a variety of potential therapies for menopausal symptoms (Table 2) and navigating the maze of options can be a challenge for the patient and clinician alike. In addition, many factors can influence the patient and health care professional because the

**TABLE 2. Treatments for Menopausal Symptoms<sup>1,18</sup>**

Category	Potential Options
Lifestyle Modifications	Nutrition Exercise Layering of clothing Smoking cessation Reduced alcohol intake Meditation Paced breathing
Hormone therapy (HT)	Transdermal preparations Oral preparations Vaginal preparations Topical sprays Compounded preparations
Over-the-counter products	Vaginal moisturizers/lubricants Complementary and alternative medicine (herbal and nutritional supplements)
Nonhormonal therapy	Selective serotonin reuptake inhibitor antidepressants Selective serotonin/norepinephrine reuptake inhibitors Gabapentin Clonidine

abundance of available information is difficult to sort through.

The type of clinician a woman sees (eg, a Women's Health nurse practitioner versus a Family Health nurse practitioner, or an internist versus a gynecologist) may impact what treatment options are offered. "Clinicians' attitudes about therapies for menopausal symptoms, hormones in particular, vary considerably," notes Dr Hess. A survey by Brett and colleagues conducted in 2002 after the publication of results from the WHI confirms this.<sup>17</sup> The survey asked clinicians to respond to a hypothetical scenario of a woman who asks whether to continue HT; gynecologists were more likely than internists to have positive views about prescribing HT (66% vs 35%;  $P < .001$ ).

Independent of attitude or practice setting, clinicians need a thorough understanding of available treatments, as well as which treatments have proven effective, to provide their postmenopausal patients with optimum care. A clinician's appreciation of a woman's preferences and an understanding of the evidence on alternative options are essential in assisting these patients make the best possible decision to meet their needs.

Patients want to drive their own treatment options with help from their clinician. "The patient's expectation is 'Relieve my symptoms, but I would like some input into my treatment. What can you tell me about it, doctor? What's its history? How is this going to affect me?'"

*Andrew London, MD*

### WHAT IS RECOMMENDED?

Hormone therapy is currently the only pharmaceutical product approved by the FDA for the treatment of menopause-related symptoms.<sup>1,18</sup> The practice of starting at the lowest effective hormone dose, continuing for the shortest duration consistent with treatment goals and risk factors, as well as routinely evaluating the need for continued therapy, is considered the standard of care.<sup>18,19</sup> The North American Menopause Society (NAMS) recommendations for the role of HT are summarized (this page).

The use of hormones to treat menopausal symptoms is well established; however, hormones may not be the option women are seeking. The literature supports a trend of women choosing complementary and alternative medicine (CAM) during menopause, including herbs, nutritional supplements, soy-rich foods, medita-

### North American Menopause Society Recommendations on the Role of Menopausal Hormone Therapy<sup>18</sup>

- Estrogen therapy (ET), with or without the use of a progestogen, is the most effective treatment for menopause-related vasomotor symptoms (ie, hot flashes and night sweats) and their potential consequences (eg, diminished sleep quality, irritability, and reduced quality of life).
- ET is the most effective treatment for moderate to severe symptoms of vulvar and vaginal atrophy (eg, vaginal dryness, dyspareunia, and atrophic vaginitis).
- When considered solely for the treatment of vulvar and vaginal atrophy, local vaginal ET is generally recommended.
- The primary menopause-related indication for progestogen use is to negate the increased risk of endometrial cancer from systemic ET use.
- Progestogen is generally not indicated when ET is administered locally for vaginal atrophy at the recommended low doses.

tion, and massage,<sup>20-22</sup> perhaps due to concerns of adverse effects from hormones or the perception of CAM as "safer" or "more natural."<sup>20</sup>

### WHAT ARE THE OPTIONS?

#### Hormones: Natural, Synthetic, or Bioidentical?

Currently, estrogen and progestogen formulations are the only FDA-approved products for menopause-related symptoms. These products are available in an array of strengths and dosage forms; Table 3 displays several of the estrogen and progestogen products currently on the US market.

Different terms have been used to describe hormone formulations. Terms such as "natural," "synthetic," "compounded," or "bioidentical" have caused much confusion for medical professionals and their patients, and consensus on the definitions of these terms is difficult to ascertain.<sup>23</sup> For example, the Endocrine Society defines "bioidentical" hormones as "compounds that have the exact same chemical and molecular structure as hormones that are produced in the human body."<sup>24</sup> By that definition, several of the FDA-approved estrogen preparations listed in Table 3 would be considered "bioidentical" because they contain estradiol, a compound with the exact same chemical and molecular structure as the estrogen produced in the human body. However, the FDA does not recognize the term "bioidentical." In comparison, ACOG defines "bioidentical" hormones as "plant-derived hormones that are biochemically similar or identical to those produced by the ovary or human body."<sup>25</sup> Menest<sup>®</sup>, Enjuvia<sup>®</sup>, Estrace<sup>®</sup>, and Cenestin<sup>®</sup> are derived from plants (soy and yams) and contain estrogens biochemically similar to estrogens produced in the body, in addition to those that are not.

TABLE 3. Estrogen and Progestogen Products for Menopause-Related Symptoms\*

Brand Name	Active Ingredient(s)	Dosage Form(s)
<b>ESTROGEN ONLY</b>		
Estrace®	Estradiol	Oral tablet, vaginal cream
Femtrace®	Estradiol	Oral tablet
Menest®	Esterified estrogens	Oral tablet
Ogen®	Estropiate (formerly piperazine estrone sulfate)	Oral tablet
Premarin®	CEE	Oral tablet, vaginal cream
Enjuvia®	Plant-derived conjugated estrogens	Oral tablet
Cenestin®	Plant-derived conjugated estrogens	Oral tablet
Estraderm®, Vivelle®, Climara®	Estradiol	Transdermal patch
Divigel®, EstroGel®	Estradiol	Transdermal gel
Femring®, Estring®	Estradiol	Vaginal ring
Vagifem®	Estradiol	Vaginal tablet
Evamist®	Estradiol	Topical spray
<b>PROGESTOGEN ONLY</b>		
Provera®	Medroxyprogesterone	Oral tablet
Aygestin®	Norethindrone	Oral tablet
Prometrium®	Micronized progesterone	Oral tablet
<b>ESTROGEN-PROGESTOGEN COMBINATIONS</b>		
CombiPatch®	Estradiol/norethindrone	Transdermal patch
Climara Pro®	Estradiol/levonorgestrel	Transdermal patch
Activella®	Estradiol/norethindrone	Oral tablet
femhrt®	Estradiol/norethindrone	Oral tablet
Prempro®	CEE/medroxyprogesterone	Oral tablet
Angeliq®	Estradiol/drospirenone	Oral tablet

\*Table is not all inclusive and generic products may be available

CEE = conjugated equine estrogens.

Hormone products mixed or prepared by a pharmacist from a licensed practitioner's prescription are considered "compounded."<sup>23,25</sup> Examples include Biest (biestrogen), containing 20% estradiol and 80% estriol; and Triest (triestrogen), containing 10% estradiol, 10% estrone, and 80% estriol. Compounded hormones are not subject to the same rigorous safety and efficacy evaluations as FDA-approved hormone products. Sellers of compounded hormones may claim their products are without the risks of FDA-approved hormones, but data to support this contention are lacking, according to 2 recent FDA consumer updates.<sup>23,26</sup> **Compounded products that are identical to synthetic hormones in their chemical make-up can be expected to have the same benefits—and risks—associated with FDA-approved hormone therapy.**<sup>23</sup>

"We believe in hormone therapies and we think they benefit most patients," says Dr Hess, "but people may prefer to use compounded products and we need to

educate them on their safe use. It is important for women to be aware that 'natural' or 'compounded' does not mean without side effects. It is our job as clinicians to educate them."

### Nonhormonal Options

Some patients may prefer treatments that do not contain hormones, either because of concerns about adverse effects or contraindications to HT (eg, breast cancer). Several nonhormonal options have been evaluated for their effects on vasomotor symptoms (Table 4). None are currently FDA-approved for this indication; however, evaluations of products to treat menopausal symptoms are summarized below.

### Nonhormonal Prescription Products

To determine the involvement of noradrenergic and serotonergic mechanisms in the treatment of vasomotor symptoms, Albertazzi conducted a review of trials that

**TABLE 4. Nonhormonal Options Evaluated for Effects on Vasomotor Symptoms**

PRESCRIPTION OPTIONS		
Brand Name (generic name)	Drug Class	Current FDA-Approved Indications
Effexor® (venlafaxine)	Antidepressant, SNRI	<ul style="list-style-type: none"> <li>Major depressive disorder</li> <li>Generalized anxiety disorder</li> <li>Social anxiety disorder</li> <li>Panic disorder</li> </ul>
Pristiq® (desvelafaxine)	Antidepressant, SNRI	<ul style="list-style-type: none"> <li>Major depressive disorder</li> </ul>
Paxil® (paroxetine)	Antidepressant, SSRI	<ul style="list-style-type: none"> <li>Major depressive disorder</li> <li>Obsessive compulsive disorder</li> <li>Generalized anxiety disorder</li> <li>Social anxiety disorder</li> <li>Panic disorder</li> <li>Posttraumatic stress disorder</li> </ul>
Prozac® (fluoxetine)	Antidepressant, SSRI	<ul style="list-style-type: none"> <li>Major depressive disorder</li> <li>Obsessive compulsive disorder</li> <li>Bulimia nervosa</li> <li>Panic disorder</li> </ul>
Zoloft® (sertraline)	Antidepressant, SSRI	<ul style="list-style-type: none"> <li>Major depressive disorder</li> <li>Obsessive compulsive disorder</li> <li>Social anxiety disorder</li> <li>Panic disorder</li> <li>Posttraumatic stress disorder</li> <li>Premenstrual dysphoric disorder</li> </ul>
Celexa® (citalopram),	Antidepressant, SSRI	<ul style="list-style-type: none"> <li>Depression</li> </ul>
Lexapro® (escitalopram)	Antidepressant, SSRI	<ul style="list-style-type: none"> <li>Major depressive disorder</li> <li>Generalized anxiety disorder</li> </ul>
Catapres® (clonidine)	Alpha2-Adrenergic agonist	<ul style="list-style-type: none"> <li>Hypertension</li> </ul>
Neurontin® (gabapentin)	Anticonvulsant	<ul style="list-style-type: none"> <li>Seizures</li> <li>Postherpetic neuralgia</li> </ul>
NONPRESCRIPTION OPTIONS*		
	Vitamin E	Black cohosh
	Isoflavones (soy-derived, red clover-derived)	Ginseng
	Soy plus black cohosh	

SNRI=serotonin/norepinephrine reuptake inhibitor; SSRI=selective serotonin reuptake inhibitor  
 \*Multiple manufacturers, product names and combinations

evaluated multiple antidepressants and their effect on hot flash reduction.<sup>27</sup> Selective serotonin reuptake inhibitors (SSRIs) reduced hot flashes by 60%, compared to a 70% to 80% reduction achieved with estrogen and a 20% to 40% reduction achieved with placebo during well-controlled trials. Similarly, Loprinzi and colleagues reported a 40% reduction in hot flashes in the first week of treatment with venlafaxine in their evaluation of its use in breast cancer survivors, and a 30% reduction as early as the first day of treatment.<sup>28,29</sup>

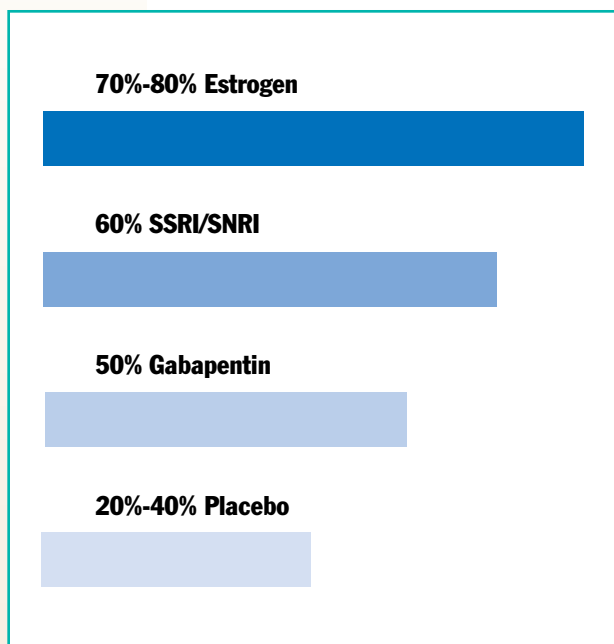
Gabapentin has been evaluated for use as a treatment for menopausal hot flashes.<sup>30</sup> In a study of 197 postmenopausal women, Butt and colleagues reported a statistically significant decrease in hot flash scores with the use of gabapentin compared to placebo; 51% versus 26% reduction, respectively ( $P < 0.001$ ). Women in the gabapentin group experienced more side effects (dizziness, unsteadiness, drowsiness) early on, but, as

the study continued, these improved and eventually returned to baseline levels.

Nonhormonal prescription options may reduce hot flashes, but data show their effectiveness to be less than that of HT (Figure). It is important to note that each nonhormonal prescription option has unique pharmacologic properties, including side effects, risks, and established or potential drug-drug interactions. Nonhormonal prescription options are not required to submit their clinical trials on menopausal symptoms to the FDA for review unless they are seeking an additional indication.

#### *Complementary and Alternative Therapies*

Alternative therapy has gained popularity with many women seeking botanicals, vitamins, dietary supplements, and other treatments to relieve their menopausal symptoms. Although not regulated by the FDA, analysis



**FIGURE.** Hot Flash Reduction with Treatment vs Placebo.<sup>20,27</sup>

SSRI = selective serotonin reuptake inhibitor; SNRI = serotonin/norepinephrine reuptake inhibitor.

of 70 randomized controlled trials of biologically-based therapies and mind-body therapies had mixed results.<sup>31</sup> The placebo effect in treating menopausal symptoms is high—up to 50% in some studies. Several studies comparing soy products to placebo found that both treatments improved hot flashes from baseline without significant differences.<sup>31</sup> A meta-analysis of 6 trials of soy isoflavones and 6 other trials of 2 types of red clover isoflavones failed to find any differences between active treatment and placebo.<sup>32</sup> A single large trial of a black cohosh formulation found benefit in treating vasomotor symptoms, while 3 other studies of black cohosh failed to show beneficial results.<sup>31</sup> Additionally, the short duration of these studies leaves the question of long-term safety of black cohosh (longer than 6 months) unanswered.<sup>33</sup> Adverse effects and safety data were inconsistently collected from studies, although one 5-year follow-up study of soy indicated that users were at higher risk of endometrial hyperplasia than users of placebo.<sup>34</sup>

It is important for clinicians to recognize that complementary and alternative therapies are of interest to many women, and they should encourage open dialogue that allows the person to disclose their use of such treatments. Dr Simon notes that clinicians should be aware of such treatments and be able to counsel their patients appropriately; helping them find information to support their therapeutic decisions goes a long way to forming a mutually beneficial therapeutic alliance. Dr London highlights that it is equally important for clinicians and their patients to be aware these therapies are not without

side effects—“natural” does not equate to a lack of side effects; there just may be a new set of side effects. Dr Hess summed up the power of patients’ beliefs in alternative therapies, stating: “When someone feels strongly about a certain option, it’s going to work because they’re into it. So I try to help them try it.”

## CONCLUSION

The menopause transition is a unique opportunity for clinicians to collaborate with their patients in developing a treatment plan for managing bothersome menopausal symptoms and for promoting lifelong general health and fitness. Several therapeutic options are available, including prescription HT; prescription nonhormonal agents; and over-the-counter vitamins, supplements, and botanicals. While the “gold standard” of HT is still the only FDA-approved treatment for menopausal symptoms, other options exist for women who are unable or unwilling to take HT. Recognizing and addressing the patient’s key concerns and being informed about all treatment options are critical to achieving a successful therapeutic outcome in menopausal patients.

*Note:* Additional content pertaining to this article can be seen online at [www.femalepatient.com](http://www.femalepatient.com), including a Menopause Impact Tool and 3 case studies.

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# Menopause Impact Tool

Patient Name: \_\_\_\_\_

Date of Birth: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

## THIS SECTION TO BE COMPLETED BY HEALTHCARE PROFESSIONAL

Date: \_\_\_\_\_

Patient Time In \_\_\_\_\_

Patient Time Out \_\_\_\_\_

Past Hysterectomy (Yes/No) \_\_\_\_\_

Menopausal (Yes/No) \_\_\_\_\_

**Patient Instructions:** Please answer the questions below prior to meeting with your healthcare professional who will review the completed questionnaire during your office visit.

Rating Scale:    1 – Not at all or rarely    2 – A little or moderately    3– Regularly or frequently

### Assessment of Vasomotor Symptoms

In the last month, to what extent have you been bothered by the following symptoms? Please rate each symptom from 1 to 3 (refer to above scale and circle your response). Then, place an "X" in ONE of the boxes to indicate which ONE symptom is most bothersome to you, or most disrupts your daily life.

Hot flashes	1	2	3	<input type="checkbox"/>
Night sweats or chills	1	2	3	<input type="checkbox"/>
Sleep disturbance	1	2	3	<input type="checkbox"/>
Joint pain or stiffness	1	2	3	<input type="checkbox"/>
Fatigue	1	2	3	<input type="checkbox"/>

To what extent have these symptoms negatively impacted the following (refer to above scale and circle your response)?

Feelings about yourself	1	2	3
Relationships	1	2	3
Work	1	2	3

\_\_\_\_\_ Total Vasomotor Symptoms Assessment Score

### Assessment of Sexual Health

In the last month, to what extent have you been bothered by the following symptoms? Please rate each symptom from 1 to 3 (refer to above scale and circle your response). Then, place an "X" in ONE of the boxes to indicate which ONE symptom is most bothersome to you, or most disrupts your daily life.

Genital Dryness, pain and/or burning	1	2	3	<input type="checkbox"/>
Pain during sexual activity	1	2	3	<input type="checkbox"/>
Decreased sexual desire	1	2	3	<input type="checkbox"/>
Decreased sexual response	1	2	3	<input type="checkbox"/>
Decreased sexual frequency	1	2	3	<input type="checkbox"/>

To what extent have these symptoms negatively impacted the following (refer to above scale and circle your response)?

Feelings about yourself	1	2	3
Relationships	1	2	3
Work	1	2	3

\_\_\_\_\_ Total Sexual Health Assessment Score

# Menopause Impact Tool

## Assessment of Psychological Symptoms

In the last month, to what extent have you been bothered by the following symptoms? Please rate each symptom from 1 to 3 (refer to above scale and circle your response). Then, place an "X" in ONE of the boxes to indicate which ONE symptom is most bothersome to you, or most disrupts your daily life.

Anxiety	1	2	3	<input type="checkbox"/>
Irritability	1	2	3	<input type="checkbox"/>
Sadness	1	2	3	<input type="checkbox"/>
Difficulty concentrating	1	2	3	<input type="checkbox"/>

To what extent have these symptoms negatively impacted the following (refer to above scale and circle your response)?

Feelings about yourself	1	2	3
Relationships	1	2	3
Work	1	2	3

\_\_\_\_\_ Total Psychological Symptoms Assessment Score

\_\_\_\_\_ Total Score for Menopause Symptoms and Impact Assessment (*Please add Total Assessment Scores from the above for Final Total*).

## Treatment Assessment

Please choose the statement that applies to you (*Check the most appropriate response*).

- \_\_\_\_\_ "I'd like to try hormone therapy for the treatment of my menopausal symptoms."  
\_\_\_\_\_ "I'd consider taking hormone therapy for the treatment of my menopausal symptoms, but I would first like to learn more."  
\_\_\_\_\_ "I've taken hormone therapy in the past for the treatment of my menopausal symptoms, but I didn't like it."  
\_\_\_\_\_ "I'll never take hormone therapy for the treatment of my menopausal symptoms."

**ASSESSMENT: SECTION TO BE COMPLETED BY YOUR HEALTHCARE PROFESSIONAL. THE INFORMATION ABOVE, INCLUDING THE TOTAL SCORE, WILL BE ANALYZED BY YOUR HEALTHCARE PROFESSIONAL.**

### NOTE TO HEALTHCARE PROFESSIONAL:

**Important:** In addition to the above, the patient's family and medical history should be reviewed and assessed in order to determine if the patient is a candidate for hormone therapy. Some, but not all, medical conditions important to identify include: hysterectomy, breast cancer, stroke, osteoporosis, venous thromboembolism (VTE), coronary artery disease (CAD) or hypertension, dementia, colon cancer.

**Suggestion:** It is suggested that the assessment questionnaire be completed again 3 – 6 months after initiating treatment to determine treatment adherence and effectiveness.

## APPENDIX II: INDIVIDUAL CASE STUDIES

### **Patient 1: Vaginal estrogen treatment for dyspareunia**

B.C. is a 54-year-old woman who has been naturally menopausal for 3 years. She has minimal hot flashes (1 to 2 per day, no sweating) and no sleep disturbances. Her husband is taking medication to treat erectile dysfunction. B.C. used over-the-counter personal lubricants in the past, but is currently experiencing declining relief and painful intercourse. This led to decreased interest in sex, although she has not discussed the issue with her husband. Her clinician prescribed vaginal estrogen cream.

B.C. used the cream for 3 days, and subsequently called her clinician to discuss the warnings described in the patient package insert. She was under the impression that vaginal estrogen products would be associated with fewer health risks than oral hormone therapy, although the insert described the same risks.

Her clinician reassured her that she was taking the lowest vaginal dose that would treat her symptoms and the product is associated with minimal systemic absorption. The clinician also shared his opinion that she could use the cream topically on the outside of the vagina (at times other than during intimacy) if she experienced pain during insertion when having sex. Other forms of hormone therapy are also available to treat dyspareunia associated with menopause, including low-dose oral estrogen tablets; however, this patient preferred a vaginal dosage form and was satisfied with her clinician's counseling.

### **Patient 2: Oral estrogen treatment for vasomotor symptoms**

S.W. is a 53-year-old woman who has been naturally menopausal for 2 years. She has difficulty sleeping with night sweats, and experiences 1 to 2 daytime hot flashes with disturbing visual facial flushing. She is also noticing difficulty concentrating, daytime fatigue, and irritability. She tried black cohosh without achieving relief.

After considering the options, S.W. and her clinician decided to try a course of daily low-dose oral estrogen tablets with a progestogen to protect the uterus. The prescribed progestogen (micronized progesterone capsules) is associated with a sedative effect, which would be beneficial for S.W.'s sleep disturbance. Consideration was given to only prescribing a nonhormonal sleeping aid; however, it was decided that hormone therapy would be more beneficial to treat the patient's vasomotor symptoms in addition to her sleep disturbance.

### **Patient 3: Nonhormonal therapy for vasomotor symptoms**

R.M. is a 54-year-old woman who had hysterectomy and surgical menopause at age 51. She took venlafaxine 75mg in the past for vasomotor symptoms without benefit and experienced sexual side effects. She switched to low-dose oral estrogen therapy and achieved relief from her vasomotor symptoms, but subsequently developed breast cancer and had to discontinue estrogen therapy.

After consideration of all the available nonhormonal therapies, R.M. and her clinician decided to try venlafaxine again. She did not experience significant sexual side effects with this course of therapy, and additionally benefited from treating her depression (due to diagnosis of breast cancer).