The Menopause Center

Bioidentical Hormone Therapy

Custom Compounded vs. Government Approved

Many types of hormone therapy are available for you to use for your menopause symptoms. These include hormones that are manufactured to be chemically identical to the naturally occurring hormones produced by your ovaries during the reproductive years, principally estradiol, progesterone, and testosterone. Many of these products are derived from natural sources, including yams or soy. Although the term bioidentical hormones often is used to refer to these identical copies of natural hormones (typically prescribed as custom mixes or compounds for an individual woman), bioidentical hormones is a term invented by marketers and has no clear scientific meaning.

Although natural hormones are not necessarily safer or more effective than other forms of estrogen and progestogen, some women prefer to use hormones after menopause that are identical to those their ovaries produced when they were younger.

If you prefer to treat your bothersome menopause symptoms with hormones that are chemically identical to those you produced naturally before menopause, ask your healthcare provider to prescribe estradiol and progesterone products that are scientifically tested and government approved. Estradiol is available as an oral tablet, skin patch, topical gel, topical spray, and vaginal ring. Low doses of estradiol used in the vagina (to treat vaginal dryness and painful intercourse but not hot flashes) are available as a vaginal tablet, cream, and ring. Progesterone is available as an oral capsule (see table below for product names).

Bioidentical custom-compounded hormones

Some healthcare providers prescribe custom-mixed (custom-compounded) bioidentical hormones containing one or more natural hormones mixed in differing amounts. These products not only contain the active hormone(s) but also other ingredients to create a cream, gel, lozenge, tablet, spray, or skin pellet. Healthcare providers who prescribe bioidentical hormones often claim that these products are more safe and effective than clinically tested and government-approved hormones produced by large pharmaceutical companies. They also may assert that bioidentical hormones slow the aging process. There is no scientific evidence to support any of these claims.

Government-approved hormone products are required by law to come with a package insert that describes possible risks and side effects. Custom-compounded hormones are not required to come with this information, but this does not mean they are safer. They contain the same active hormones (such as estradiol and progesterone), so they share the same risks.

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Custom-compounded hormones allow for individualized doses and mixtures; however, this may result in reduced efficacy or greater risk. These compounds do not have government approval because individually mixed recipes are not tested to verify that the right amount of hormone is absorbed to provide predictable hormone levels in blood and tissue. If you have a uterus, there are no studies showing that the amount of progesterone in these custom-mixed hormones is enough to protect you from developing uterine cancer.

There is a long history of pharmacies providing a wide range of compounded products, typically when an equivalent government-approved product is not available. Because preparation methods vary from one pharmacist to another and between pharmacies, you may receive different amounts of active medication every time you fill the prescription. Inactive ingredients may vary from batch to batch as well. Sterile production technique and freedom from undesired contaminants are additional concerns. Expense is another issue, because most custom-compounded preparations are viewed as experimental drugs and are not covered by insurance plans.

Recommendations for natural hormone therapy options

If you prefer to use hormones for your menopause symptoms that are identical to the hormones you produced naturally before menopause, ask your healthcare provider for government-approved products containing estradiol and progesterone. There is no benefit to using custom-compounded hormones, and there may be additional risks.

Government-approved natural hormone therapy products

Systemic doses of estradiol/progesterone for treatment of hot flashes

- Estradiol oral tablet: Estrace, generics
- Estradiol skin patch: Alora, Climara, Esclim, Menostar, Vivelle (Dot), Estraderm, generics
- Estradiol skin gel/cream: EstroGel, Elestrin, Divigel, Estrasorb
- Estradiol skin spray: Evamist
- Estradiol vaginal ring: Femring
- Progesterone oral tablet: Prometrium, generics
- Estradiol plus progesterone combined oral capsule: Bijuva

Low doses of vaginal estradiol for treatment of vaginal dryness and pain with intercourse

- Vaginal cream: Estrace vaginal cream
- Vaginal ring: Estring
- Vaginal tablet: Vagifem
- Vaginal insert: Imvexxy

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Menopause and Depression

Sensitivity to reproductive events

In addition to the physical changes (hot flashes, night sweats, and vaginal dryness) that may happen as you transition into menopause, many women experience mood changes, depressive symptoms, and sometimes, severe depression during this time. Although each woman is different, many women have found that they are very sensitive to changes in hormone levels. These women may experience increases in symptoms such as depression and/or anxiety during times of hormone changes, such as during the premenstrual period, pregnancy, and after having a baby (postpartum), as well as during the menopause transition or perimenopause. Like many women, you may find that you are experiencing depressive symptoms as you transition through menopause.

Depressive and menopause symptoms

Depressive symptoms may include being sad and anxious, not being interested in or enjoying your usual activities, being very tired and lacking energy, experiencing sleep problems and appetite changes, feeling hopeless and worthless, and having thoughts of death or suicide. Depression, which also is described as a major depressive disorder or clinical depression, is a serious disorder that affects your daily life and activities. If you have these symptoms for 2 weeks or longer, you may be diagnosed with depression. It is important to note that not all midlife women experience mood problems, but some women are more vulnerable than others to developing either depressive symptoms or an episode of clinical depression during the menopause transition, especially those women who have had depression previously.

The menopause transition is a time of physical and psychological change for many midlife women. Often the symptoms you may experience during perimenopause, such as hot flashes, night sweats, sleep and sexual disturbances, weight and energy changes, and memory lapses, can overlap with symptoms of depression, so it may be difficult for your healthcare practitioner to diagnose and treat you accordingly. In addition, you may be experiencing life stressors (changing lifestyle, aging parents, children leaving or returning home, financial issues, body image, and relationship problems) during midlife that may affect your mood.

Recognizing depressive symptoms and depression

When you are transitioning into menopause, you should notify your healthcare practitioner whether you have suffered from depression in the past or whether you were particularly sensitive to hormone changes and have experienced premenstrual syndrome or postpartum depression. Be alert and notice whether these mood changes are mild and do not greatly affect your quality of life or whether they are severe and debilitating and interfere with your daily activities. Your healthcare practitioner will be aware of the factors that can put you at risk for depressive symptoms or even a severe depression during this time and can do an appropriate evaluation. This may include

identifying what menopause stage you are in, assessing both your menopause and depressive symptoms, considering any additional risk factors you may have, and in some cases, asking you to complete a test to screen you for depression.

Treatment

Treatment will vary depending on whether you are suffering from mood symptoms or experiencing clinical depression. If you are having a major depressive episode, therapies that have been proven to help depression, such as antidepressants, cognitive behavior therapy, and other types of psychotherapy, will be recommended.

- **Antidepressants.** There are several antidepressant medications that have been shown to be effective and well tolerated. If you have had medication in the past that was helpful in treating depression, your healthcare practitioner will probably choose the same medication if the depression reoccurs during perimenopause. For those midlife women who are experiencing clinical depression for the first time, the effectiveness of the antidepressant medications, their side effects, and how they interact with the other medications you take will be considered. Many antidepressants used to treat menopause-related depression also have been shown to help improve menopause symptoms such as hot flashes. It also may be helpful to treat the sleep disturbances and night sweats that can occur at the same time as your depressive symptoms.
- **Psychotherapy.** Most healthcare practitioners will recommend some type of psychotherapy such as cognitive behavior therapy either alone or in combination with your antidepressant medication. Psychotherapy also will help you to cope with the stresses and losses that you may be experiencing during midlife.
- **Estrogen therapy.** Although FDA has not approved estrogen therapy to treat mood disorders, researchers have found that it may be almost as effective as the antidepressant medications typically used to treat depression in perimenopausal women, even when they're not suffering from hot flashes. Estrogen therapy also seems to improve mood and well-being in perimenopausal women, including those who are not depressed. However, estrogen therapy isn't effective for treating depression in postmenopausal women. In addition, since most of the research only examined the effect of estrogen alone, more information is needed about different hormone therapies and combination regimens.
- **Complementary medicine.** There is not enough evidence to support whether complementary/alternative medicine, herbs, or supplements help to treat depression in perimenopausal women, but the consensus is that exercise may be useful in alleviating depressive symptoms.

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Deciding About Hormone Therapy Use

Many women experience hot flashes, vaginal dryness, and other physical changes with menopause. For some women, the symptoms are mild and do not require any treatment. For others, symptoms are moderate or severe and interfere with daily activities. Hot flashes improve with time, but some women have bothersome hot flashes for many years. Menopause symptoms often improve with lifestyle changes and nonprescription remedies, but prescription therapies also are available, if needed. Government-approved treatments for bothersome hot flashes include hormone therapy (HT) containing estrogen, as well as a nonhormone medication (paroxetine).

Hormone therapy involves taking estrogen in doses high enough to raise the level of estrogen in your blood in order to treat hot flashes and other symptoms. Because estrogen stimulates the lining of the uterus, women with a uterus need to take an additional hormone, progestogen, to protect the uterus. Women without a uterus just take estrogen. If you are bothered only by vaginal dryness, you can use very low doses of estrogen placed directly into the vagina. These low doses generally do not raise blood estrogen levels above postmenopause levels and do not treat hot flashes. You do not need to take a progestogen when using only low doses of estrogen in the vagina. (The MenoNote “Vaginal Dryness” covers this topic in detail.)

Every woman is different, and you will decide about whether to use HT based on the severity of your symptoms, your personal and family health history, and your own beliefs about menopause treatments. Your healthcare professional will be able to help you with your decision.

Potential benefits

Hormone therapy is one of the most effective treatments available for bothersome hot flashes and night sweats. If hot flashes and night sweats are disrupting your daily activities and sleep, HT may improve sleep and fatigue, mood, ability to concentrate, and overall quality of life. Treatment of bothersome hot flashes and night sweats is the principal reason women use HT. Hormone therapy also treats vaginal dryness and painful sex associated with menopause. Hormone therapy keeps your bones strong by preserving bone density and decreasing your risk of osteoporosis and fractures. If preserving bone density is your only concern, and you do not have bothersome hot flashes, other treatments may be recommended instead of HT.

Potential risks

As with all medications, HT is associated with some potential risks. For healthy women with bothersome hot flashes aged younger than 60 years or within 10 years of menopause, the benefits of HT generally outweigh the risks. Hormone therapy might slightly increase your risk of stroke or blood clots in the legs or lungs (especially if taken in pill form). If started in women aged older than 65 years, HT might increase the risk of dementia. If you have a uterus and take estrogen with progestogen, there is no increased risk of cancer of the uterus. Hormone therapy (combined estrogen and progestogen) might slightly increase your risk of breast cancer if used for more than 4 to 5 years. Using estrogen alone (for women without a uterus) does not increase breast cancer risk at 7 years but may increase risk if used for a longer time.

Some studies suggest that HT might be good for your heart if you start before age 60 or within 10 years of menopause. However, if you start HT further from menopause or after age 60, HT might slightly increase your risk of heart disease. Although there are risks associated with taking HT, they are not common, and most go away after you stop treatment.

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Potential adverse events

Hormone therapy can cause breast tenderness, nausea, and irregular bleeding or spotting. These adverse effects are not serious but can be bothersome. Reducing your dose of HT or switching the form of HT you use often can decrease adverse effects. Weight gain is a common problem for midlife women, associated with both aging and hormone changes. Hormone therapy is not associated with weight gain and may lower the chance of developing diabetes.

Hormone therapy options

Each woman must make her own decision about HT with the help of a healthcare professional. If you decide to take HT, the next step is to choose between the many HT options available to find the best dose and route for you. With guidance from your healthcare professional, you can try different forms of HT until you find the type and dose that treats your symptoms with few adverse effects.

Pill or non-pill

Hormone therapy is available as a daily pill, but it also may be taken as a skin patch, gel, cream, spray, or vaginal ring. Non-pill forms may be more convenient. Hormone therapy pills need to be taken every day, but skin patches are changed only once or twice weekly, and the HT vaginal ring is changed only every 3 months. Hormone therapy taken in non-pill form enters your blood stream more directly, with less effect on the liver. Studies suggest that this may lower the risk of blood clots in the legs and lungs compared with HT taken as a pill.

Estrogen alone or estrogen plus progestogen

If you have a uterus, you will need to take progestogen with your estrogen. Many pills and some patches contain both hormones together. Otherwise, you will need to take two separate hormones (eg, estrogen pill with progestogen pill or estrogen patch with progestogen pill). Taking both hormones every day usually results in no bleeding. Women who prefer regular periods can take estrogen every day and progestogen for about 2 weeks each month. Another option is to take estrogen combined with a nonhormone medication (bazedoxifene) to protect the uterus. If you do not have a uterus, you can take estrogen alone, without a progestogen.

Dose of estrogen

As with all medications, you should take the lowest dose of estrogen that relieves your hot flashes. You can work with your healthcare professional to find the right dose for you. It typically takes about 8 to 12 weeks for HT to have its full effect, so doses should be adjusted slowly. Even low doses of estrogen will preserve your bone density and reduce your risk of a fracture.

Stopping hormone therapy

There is no “right” time to stop HT. Many women try to stop HT after 4 to 5 years because of concerns about potential increased risk of breast cancer. Other women may lower doses or change to non-pill forms of HT. Hot flashes may or may not return after you stop HT. Although not proven by studies, slowly decreasing your dose of estrogen over several months or even over several years may reduce the chance that your hot flashes will come back. You and your healthcare professional will work together to decide the best time to stop HT. If very bothersome hot flashes or night sweats return when you stop HT, you will need to reassess your individual risks and benefits to decide whether to continue HT. Because there may be greater risks with longer duration of use and as you age, you and your healthcare professional will work together to decide what is the best option for you.

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Treating Hot Flashes

Hot flashes are the most common bothersome symptom of menopause. Your hot flashes may occur during the day or at night (also known as night sweats). Your hot flashes may be mild and tolerable, moderate and troublesome, or severe and debilitating. Hot flashes get better with time. Although most women have hot flashes for a few years, some women have them for decades. It is not known why some women have severe hot flashes for many years while others have no hot flashes or mild ones that resolve quickly. If your hot flashes are mild or moderate, you may find relief by changing your lifestyle. If you have severe hot flashes, you may still benefit from lifestyle changes, but also may choose to take a nonprescription remedy or a prescription medication, including hormones to help you manage your symptoms.

Lifestyle changes

Researchers find that women with hot flashes have more sensitive thermostats in their brain, so are comfortable only in a small range of temperatures. Staying cool and reducing stress are the principal lifestyle changes to treat your hot flashes. Some women can find relief with these options:

- Avoid warm rooms, hot drinks, hot foods, alcohol, caffeine, excess stress, and cigarette smoking. Wear layers of clothing made from light, breathable fabrics, removing a layer or two when you're hot and replacing them when you're cooler. Cooling products, including sprays, gels, and the Chillow pillow may be helpful.
- To reduce stress and promote more restful sleep, exercise regularly, but not too close to bedtime. Meditation, yoga, qigong, tai chi, biofeedback, acupuncture, or massage also will lower your stress levels.
- When a hot flash is starting, try "paced respiration"—slow, deep, abdominal breathing, in through your nose and out through your mouth. Breathe only 5 to 7 times per minute, much more slowly than usual.
- Try different strategies to stay cool while sleeping. Dress in light, breathable nightclothes. Use layered bedding that can be easily removed during the night. Cool down with a bedside fan. Keep a frozen cold pack or bag of frozen peas under your pillow, and turn the pillow often so that your head is always resting on a cool surface. If you wake at night, sip cool water. Try different techniques for getting back to sleep, such as meditation, paced respiration, or getting out of bed and reading until you become sleepy.
- Women who are overweight have more hot flashes, so maintain a healthy weight and exercise regularly to decrease bothersome hot flashes and improve your overall health.

Nonprescription remedies

Although many nonprescription remedies reduce hot flashes, it's likely that this is because of the "placebo effect." When nonprescription treatments are studied scientifically, they typically are as effective as a placebo (inactive medication). Even if relief is because of the placebo effect, you can expect your hot flashes to decrease by approximately 30% with most nonprescription remedies such as soy, herbs, or acupuncture. Nonprescription products do not receive careful oversight from the government and generally are not studied carefully enough to know all potential risks and side effects, especially with long-term use. Consider purchasing products made in North America that follow good manufacturing practices. Let your healthcare provider know if you are taking a nonprescription remedy.

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Nonprescription remedies you may consider for hot flash relief include:

- **Soy:** Eat one or two servings of soy foods daily (containing isoflavones), such as low-fat varieties of tofu, tempeh, soymilk, or roasted soy nuts. Supplements containing soy isoflavones, such as Promensil, reduce hot flashes in some studies.
- **Herbs:** Supplements containing certain herbs like black cohosh, such as Remifemin, decrease hot flashes in some studies.

Prescription therapies

The following prescription medications reduce hot flashes more than placebos in scientific studies. They may be good options if you have frequent, bothersome hot flashes. Every medication has risks and side effects. Review your medical history with your healthcare provider when considering a prescription medication.

Hormone options

- Prescription hormone therapy with estrogen is the most effective treatment for hot flashes. Although using hormones can increase your risk of breast cancer and cardiovascular disease, studies show that benefits may outweigh risks for healthy women younger than age 60 with moderate to severe hot flashes. The goal is to use the lowest dose of hormone therapy that treats your symptoms for the shortest time necessary. Women with a uterus need to combine estrogen with a progestogen.
- A new option for women with a uterus combines estrogen with bazedoxifene to protect the uterus (Duavee). Bazedoxifene is an estrogen agonist/antagonist, which means it works like estrogen in some tissues and opposes estrogen's actions in others.
- If it has not been a full year since your last period and you are a healthy nonsmoker, you may consider a combination estrogen-progestin birth control pill. This will provide contraception, hot flash relief, and regular periods.

Nonhormone options

You also may consider nonhormone medications. They are more effective than placebo in scientific studies, although not as effective as hormone therapy. Low-dose paroxetine (Brisdelle) is the only government-approved nonhormone option for treating hot flashes.

- Certain drugs approved to treat depression reduce hot flashes in women without depression. Effective drugs include paroxetine (Paxil), venlafaxine (Effexor), and escitalopram (Lexapro). You should not take paroxetine if you take tamoxifen for breast cancer.
- Gabapentin (Neurontin) is a drug approved to treat epilepsy, migraine, and nerve pain, but it also reduces hot flashes. It can cause excessive sleepiness, so it is an especially good option if you have bothersome night sweats and take your gabapentin at bedtime.
- Sleeping medications such as Ambien, Lunesta, and Benadryl will not reduce your hot flashes but may help you sleep through them. Available by prescription and nonprescription.

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Menopause and Sleep Problems

Some women experience menopause-related sleep problems, especially if hormone changes cause hot flashes or sweats during the night. Lack of sleep and poor-quality sleep can make you tired, irritable, and moody. When you are tired, you may have difficulty concentrating, remembering things, working efficiently, and coping with daily stresses. You may be less patient with family and friends. Difficulty coping can lead to more stress, which can make sleep problems even worse. Adequate sleep is required for good health.

You have had enough sleep when you can function in an alert state during waking hours. Most adults need between seven and nine hours of sleep each night. During the menopause transition, you may find that you have more trouble falling asleep, staying asleep, or waking up feeling refreshed. These interventions may improve your sleep:

Lifestyle changes

- Maintain an environment that promotes sleep. Think quiet, cool, and dark. A white noise machine may be helpful. If you have night sweats, try a bedside fan, light pajamas and bedding, and placing an ice pack under your pillow—turning the pillow over during the night so that your face rests on the cool side.
- Try relaxation techniques such as meditation or slow deep-breathing exercises. You can learn these techniques through books, videos, and classes.
- Avoid TV, computer screens, smart phones, and electronic readers for at least an hour before bedtime, because the light from these devices may disrupt sleep.
- Follow the 15-minute rule. If you do not fall asleep within 15 minutes, get up, leave the bedroom, and do something relaxing in another room, such as reading a book or magazine or listening to quiet music. Return to bed when you are drowsy.
- Follow a regular sleep routine. Try to wake up and go to bed at about the same time each day, even on weekends.
- Use the bedroom only for sleep and sex.
- Avoid stimulants such as alcohol, caffeine, and nicotine throughout the entire day, not just during the evening. Although alcohol is initially a sedative, it often results in disrupted sleep. The stimulant effects of caffeine may last up to 20 hours. Coffee, tea, and cola are not the only culprits. Many pain relievers, diuretics, allergy and cold medications, and weight-control aids also contain caffeine.
- Avoid eating a large meal or sweets right before bedtime. This may disrupt sleep—and also promote weight gain.
- If your sleep is disrupted by your partner's late-night activities or snoring, discuss how this is affecting your sleep and consider solutions. Snoring may be a sign of sleep apnea, so your partner may benefit from seeing his or her healthcare provider.
- Exercise almost every day. Daily exercise improves sleep, but avoid strenuous exercise close to bedtime.
- If your sleep problems do not respond to lifestyle changes, consult your healthcare provider about other treatment options and to rule out specific causes of sleep

problems such as thyroid abnormalities, depression, anxiety, allergies, restless leg syndrome, or sleep apnea (breathing problems during sleep). Women with serious sleep disturbances may benefit from consultation with a sleep specialist.

Treatments

- **Herbs and supplements:** Melatonin, valerian, chamomile, lavender, lemon balm, and passion flower may be mild sedatives, although scientific data are limited. Government oversight of herbs and supplements is limited, so purchase products made in the United States under good manufacturing practices.
- **Over-the-counter sleep aids:** Many contain diphenhydramine (e.g., Benadryl) and may help you fall asleep and stay asleep. Try low doses (25 mg or less) to reduce the risk of morning grogginess.
- **Cognitive behavioral therapy (CBT):** CBT is a specific form of psychotherapy that effectively treats many sleep problems.
- **Prescription sleep medications:** Medications approved to treat sleep problems may be helpful to break a cycle of insomnia but ideally should be used only as a short-term solution. Some result in morning fatigue, they can become less effective over time, and they can be habit forming. The grogginess associated with sleep medications can increase the risk of falls, so try to avoid sleep medications if you are at increased risk of falling.
- **Treatments for night sweats:** If you have bothersome hot flashes and/or night sweats that disrupt sleep, consider treating your nighttime symptoms to improve your sleep. Effective treatments for night sweats include hormone therapy and nonhormonal medications such as certain low-dose antidepressants. Hormone therapy has other benefits and risks, so you should speak with your healthcare provider to see whether hormones or other medications that treat night sweats are right for you.
- With any medication you choose for sleep, always use the lowest dose that treats your sleep problems for the shortest time needed.

For more information about sleep problems, review Your Guide to Healthy Sleep (**nhlbi.nih.gov/files/docs/public/sleep/healthy_sleep.pdf**) from the National Heart, Lung, and Blood Institute, as well as the National Sleep Foundation website, **sleepfoundation.org**.

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Postmenopausal Osteoporosis

What are osteoporosis and osteopenia?

Osteoporosis is a thinning of bones caused by a decrease of bone density beginning around the time of menopause. Bone loss is particularly rapid in the 5 to 10 years around the menopause transition because of loss of estrogen. During that rapid bone loss, the delicate structure of the skeleton is damaged, weakening the bone, increasing the risk of a broken bone or fracture. Osteoporosis is a risk factor for all fractures except those of the face, hands, and feet. Other important risk factors for fracture include older age, frequent falls, and a history of previous fracture, especially if the fracture happened in the previous year. In addition, many medical conditions such as celiac disease and medicines such as prednisone and aromatase inhibitors may contribute to bone loss and osteoporosis. The diagnosis of postmenopausal osteoporosis is made in women who have had a spine or hip fracture or who have a T-score of −2.5 or less on a bone density test. Postmenopausal women with T-scores between −1.0 and −2.5 have low bone density or osteopenia. This category includes many women with low normal bone density who are at low fracture risk but also includes older women who have other risk factors placing them at high risk.

Who should be tested?

Bone density testing and fracture risk assessment should be performed in all postmenopausal women with risk factors for osteoporosis. This includes all postmenopausal women who have had a fracture, all women aged 65 years or older, and younger postmenopausal women with other risk factors including being thin, a family history of osteoporosis, smoking, or diseases or medicines that harm the bones.

How can osteoporosis be prevented?

General measures, including a healthy diet, regular weightbearing activities such as walking, and avoiding harmful habits such as smoking, are important for bone health. A daily intake of 1,000 mg to 1,200 mg of calcium is recommended. For women with low dairy intake, supplements of 600 mg calcium daily may be useful (a dairy-free diet usually contains about 300 mg of calcium). Vitamin D supplements of 1,000 IU to 2,000 IU daily are recommended for women known to have osteoporosis and for those at risk for vitamin D deficiency, including marked obesity or gastrointestinal problems affecting absorption. Higher doses of calcium and vitamin D are not helpful. Weight-bearing activity can slow bone loss, especially in older women, but none of these general measures can prevent the bone loss that happens around menopause, and none are adequate treatment for osteoporosis.

Estrogen therapy should be considered to prevent bone loss in younger postmenopausal women at risk for osteoporosis, especially in women with menopause symptoms. Bone loss happens quickly when estrogen is stopped but can be prevented by switching to a bisphosphonate, a drug approved for osteoporosis prevention and treatment for a few years. For women who cannot take estrogen, bisphosphonates can prevent the rapid bone loss in early menopause and for some women may only be needed for a few years.

How is osteoporosis treated?

For women with osteoporosis, drug therapy, in addition to the general measures noted earlier, is necessary to strengthen the skeleton and decrease the risk of fracture. Because the benefits of all treatments go away when the drugs are stopped, managing osteoporosis requires long-term treatment. For most patients, using different drugs in various sequences is the best way to treat osteoporosis.

Raloxifene is an antiestrogen approved for the prevention and treatment of osteoporosis. It is less potent than the other bone medications and does not completely prevent bone loss in early menopause or prevent hip fractures in women with osteoporosis. Raloxifene is also approved to prevent breast

cancer in high-risk women. It increases hot flashes in some women but is an option for women with osteoporosis who are at high risk for breast cancer but not for hip fracture.

Bisphosphonates and *denosumab* are the drugs most often used to treat osteoporosis. They work by slowing the activity of both the bone-dissolving cells and the bone-forming cells. These drugs increase bone density (4%-10% over 3 years), strengthen the bones, and significantly decrease the risk of spine, hip, and other fractures, but they do not rebuild the damaged bone structure.

Bisphosphonates are available as tablets taken once weekly or monthly or as an intravenous infusion given once yearly or less often. Side effects of oral bisphosphonates include stomach upset and muscle pains, which are usually mild and temporary. Flu-like symptoms can occur after the first dose of intravenous bisphosphonates but rarely occur with the next doses and can be minimized with acetaminophen. Bisphosphonates have been associated with poor healing after a dental implant or tooth extraction, a rare condition called osteonecrosis of the jaw. The risk of that happening is decreased by good dental hygiene before and careful prevention of infection during the procedure. The risk of unusual (atypical) fractures is very low during the first 5 years of bisphosphonate therapy but increases to about 1 in 1,000 patients after 8 to 10 years of treatment. Limiting bisphosphonate therapy to no more than 5 years at a time minimizes that risk. After 3 to 5 years of treatment, bisphosphonates can be temporarily stopped for a few years in women at modest risk of fracture. However, for patients who remain at high risk of fracture, continuing treatment with a different drug is usually considered.

Denosumab, a human antibody, is given as an injection every 6 months and can be used for many years. Bone density increases over at least 10 years of treatment. Side effects may include skin rash and hypersensitivity (allergy-like) reactions. Concern about an increased risk of infection was not observed in a large 10-year study. As with estrogen, bone density decreases rapidly, and protection from spine fractures is quickly lost when denosumab is stopped unless treatment with a bisphosphonate is begun.

Osteoanabolic agents (bone-building drugs), including *teriparatide, abaloparatide,* and *romosozumab*, stimulate new bone formation and rebuild bone structure. Bone-building drugs are more effective than bisphosphonates at increasing bone density and reducing fractures. They are recommended for patients at very high risk of fracture, including older women with very-low bone density or with recent or multiple fractures. These drugs are given for 12 to 24 months at a time and are then followed by either a bisphosphonate or denosumab to maintain the bone-building benefits.

Fall prevention

Most fractures happen after a fall. Programs to improve muscle strength and balance such as Tai Chi, correcting poor vision, and removing fall hazards from the home can reduce fall risk.

Summary

All postmenopausal women experience bone loss and are at risk for osteoporosis. Estrogen therapy can prevent osteoporosis when started at the time of menopause. For women with osteoporosis, multiple treatment options are available that quickly and safely reduce the risk of painful and serious fractures.

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The Menopause Center

Vaginal Dryness

The genitourinary syndrome of menopause (GSM) includes bothersome vaginal, vulvar (lips of the vagina), and urinary symptoms that can affect quality of life, sexual satisfaction, and even your relationship with your partner. Unlike hot flashes, which typically improve with time, GSM usually worsens over time without treatment.

Menopause and aging can affect the vagina in the following ways:

- Loss of estrogen at menopause may cause the vaginal tissues to become thin and dry, with decreased elasticity and lubrication, often resulting in pain with sexual activity, routine pelvic examinations, and even discomfort wiping after urination or wearing certain clothing.
- Symptoms such as burning, itching, or irritation of the vulva; lack of lubrication and vaginal dryness; and discomfort or pain with sexual activity are common.
- Burning on urination, increased frequency or urgency of urination, and increased risk for urinary tract infections also can occur.
- Symptoms may be more severe in women who undergo menopause as a result of the surgical removal of both ovaries (surgical menopause) or because of chemotherapy for cancer treatment and in those who receive aromatase inhibitors for prevention or treatment of breast cancers.

Treatment options

There are many effective treatment options for GSM, including over-the-counter and prescription therapies. Firstline therapies for less severe symptoms include nonhormone over-the-counter lubricants used as needed for sexual activity and moisturizers used regularly (several times per week) to maintain moisture. Prescription therapies include low-dose vaginal estrogens, vaginal dehydroepiandrosterone inserts, and oral ospemifene. Nonhormone lubricants and moisturizers can be combined for optimal symptom relief and can be used in combination with prescription therapies for more severe symptoms.

Non-hormone remedies

- **Vaginal lubricants** can be used with sexual activity to reduce discomfort and increase pleasure by decreasing friction. These include water-, silicone-, and oil-based products. Oil-based lubricants may damage condoms and may increase the risk of vaginal infections. Lubricants should not contain flavors (sugar), warming properties, or solvents and preservatives such as propylene glycol and parabens that may cause irritation in some women.
- **Vaginal moisturizers** are used regularly, often several times weekly to maintain vaginal moisture, with a goal of reducing the daily symptoms of GSM.
- **Regular sexual stimulation** promotes vaginal blood flow and secretions. Sexual stimulation with a partner, alone, or with a device (such as a vibrator) can improve vaginal health.
- **Expanding your views of sexual pleasure** to include "outercourse" options such as extended caressing, mutual masturbation, and massage provide a way to remain sexually intimate in place of intercourse.
- **Vaginal dilators** can stretch and enlarge the vagina if it has become too short and narrow or if involuntary tightening occurs, preventing comfortable sexual activity. Dilators can be purchased and used with the guidance of a gynecologist, physical therapist, or sex therapist. You can find dilators online or at specialty stores.
- **Pelvic floor exercises** can strengthen weak pelvic floor muscles and relax tight ones. Pelvic floor physical therapy is available with trained therapists or there are at-home devices to help strengthen the pelvic floor and treat incontinence.

Vaginal hormone therapy

- An effective and safe treatment, **low-dose local estrogen** applied directly to the vagina relieves vaginal dryness and discomfort with sexual activity. Improvements usually occur within a few weeks or months with consistent use.

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- **FDA-approved low-dose vaginal estrogen products** are available by prescription as vaginal creams (used two or three nights/wk), a vaginal estradiol tablet or insert (used twice/wk), and an estradiol vaginal ring (changed every 3 months).
- **Dehydroepiandrosterone** (DHEA; prasterone) is a hormone-containing insert placed in the vagina nightly that reduces vaginal dryness and discomfort with sexual activity.
- Low-dose vaginal estrogen or DHEA may be options for women with a history of breast or uterine cancer after careful consideration of risks and benefits in collaboration with their primary care professionals and their oncologists.

Systemic estrogen therapies

Systemic estrogen therapy provided for treatment of hot flashes also treats vaginal dryness, although some women still benefit from additional low-dose vaginal hormone treatment. If only vaginal symptoms are present, low-dose vaginal hormone treatments are recommended.

Other therapies

Ospemifene is a prescription selective estrogen receptor modulator (SERM) available as an oral tablet taken daily for the treatment of vaginal dryness and sexual pain.

Vaginal laser therapy such as fractional CO2 laser or radiofrequency devices are FDA cleared for vaginal use but not specifically for treatment of GSM. Treatments are costly and generally not covered by insurance. Additional, longer-term studies are needed to establish efficacy and safety before these therapies can be routinely recommended for treatment of GSM.

Note: Vaginal and vulvar symptoms not related to menopause include yeast infections, allergic reactions, and certain skin conditions, so consult your healthcare professional if symptoms do not improve with treatment. Compounded vaginal estrogen and testosterone are not FDA regulated or recommended for treatment of GSM in most cases.

Treatment options summary

Vaginal lubricants (nonprescription).
Many available products.

Vaginal moisturizers (nonprescription).
Many available products.

Vaginal estrogen therapy (prescription required)
- Estrace or Premarin vaginal cream (0.5-1 g, placed in vagina 2-3 times/week; generic available).
- Estring (small, flexible estradiol ring placed in vagina and changed every 3 months; 7.5 µg/d).
- Vagifem (estradiol tablet placed in vagina twice/week; 10 µg; generic available).
- Imvexxy (estradiol softgel insert placed in vagina twice/week; 4 µg, 10 µg).

Intravaginal dehydroepiandrosterone
(Intrarosa; prescription required).
- A 6.5 mg vaginal insert used nightly.

Ospemifene (Osphena; prescription required).
- Oral 60 mg tablet taken once daily.

Vaginal "exercise"
- Sexual activity (with or without a partner).
- Stretching exercises with lubricated vaginal dilators.
- Pelvic floor physical therapy.

This MenoNote, developed by the NAMS Education Committee of The NorthAmerican Menopause Society, provides current general information but not specific medical advice. It is not intended to substitute for the judgment of a person's healthcare professional. Additional information can be found at www.menopause.org.

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