To help doctors provide the best possible care, the American Society of Clinical Oncology (ASCO) asks its medical experts to develop recommendations for specific areas of cancer care. This guideline was updated in 2013 to add new evidence about the benefits and risks of using medications (pills) as a way to lower the risk of breast cancer for women. In addition, a recommendation that doctors should discuss exemestane (Aromasin), as an alternative to tamoxifen and/or raloxifene, was added in this update. This guide is based on ASCO’s latest recommendations.

LEARNING ABOUT YOUR RISK
ASCO developed this guideline to provide recommendations for the use of drugs to help lower the risk of breast cancer for women who have a high risk of the disease. Women who have a high risk are those with lobular carcinoma in situ (LCIS) and those whose five-year risk of breast cancer is 1.66% or higher as calculated by the Breast Cancer Risk Assessment Tool from the National Cancer Institute (NCI) at www.cancer.gov/bcrisktool. This tool uses your age, race, and medical history, including whether you have had a breast biopsy, when you first started your menstrual period, if or when you gave birth, and whether any of your first-degree relatives (mother, sisters, daughters) have had breast cancer to estimate a risk. There are other tools used to estimate breast cancer risk, talk with your doctor about how your predicted risk of breast cancer is calculated and what it means.
DRUGS USED TO LOWER BREAST CANCER RISK
Several drugs have been studied as a way to reduce breast cancer risk. These drugs are most effective for lowering the risk of estrogen (ER)-positive breast cancer, which means that the cancer depends on the hormone estrogen to grow.

Tamoxifen (Nolvadex, Soltamox) is a type of drug called a selective estrogen receptor modulator (SERM). It is often used as a treatment for breast cancer for women who already have the disease. Tamoxifen blocks the effects of estrogen on tumor growth. It has been shown to lower the risk of breast cancer recurrence (cancer that comes back after treatment) and lengthen the lives of women with early-stage breast cancer.

The side effects of tamoxifen may include hot flashes, vaginal discharge, and a higher risk of developing uterine cancer, blood clots, and stroke.

Raloxifene (Evista) is also a SERM. It is often used to prevent osteoporosis (thinning of the bones) for women who have gone through menopause. Recent research shows that raloxifene lowers the risk of breast cancer for women who have been through menopause.

The side effects of raloxifene may include hot flashes, leg cramps, swelling of the legs and arms, weight gain, stroke, blood clots, and pain during sexual intercourse. Women taking raloxifene are less likely to develop blood clots, noncancerous conditions of the uterus, and cataracts than women taking tamoxifen.

Exemestane is a drug known as an aromatase inhibitor (AI). AIs are a type of hormone treatment that reduces the amount of estrogen in a woman’s body by stopping tissues and organs other than the ovaries from producing estrogen. Exemestane is only for women who have gone through menopause. Exemestane is not approved at this time by the U.S. Food and Drug Administration for lowering breast cancer risk in women who do not have the disease. However, it is approved for treating breast cancer.

QUESTIONS TO ASK THE DOCTOR
To learn more about the use of drugs to reduce your risk of breast cancer, talk with your doctor about your risk of developing breast cancer, your medical history, your overall health, and the risks and benefits of such drugs. Consider asking the following questions:
• What is my short- and long-term risk of getting breast cancer? How is my risk calculated?
• How does my risk compare to the average women’s risk?
• What should I do if I know I’m at risk for breast cancer?
• Have I been through menopause? How does this affect the use of drugs to reduce the risk of breast cancer?
• How does taking one of these drugs lower my risk of breast cancer?
• Would it help me to take one of these drugs to reduce my risk of breast cancer?
• Are there other ways to reduce my risk of breast cancer?
• What are the additional benefits of each of these drugs?
• What are the side effects of each drug? How could these affect my quality of life?
• What can be done to help me manage these side effects if they do occur?
• What other factors may help guide the decision to take drugs to lower the risk of breast cancer?
• What clinical trials are open to me?
• Where can I find more information to help me make a decision about drugs to reduce the risk of breast cancer?
The side effects of exemestane may include hot flashes, fatigue, sweating, difficulty sleeping, diarrhea, nausea, joint and muscle pain, and bone loss.

**RECOMMENDATIONS FOR LOWERING BREAST CANCER RISK**

- There are different recommendations for the use of drugs to reduce the risk of breast cancer depending on whether you have been through menopause. Menopause is the time when the ovaries stop producing eggs and menstrual periods have stopped for 12 months in a row. For a woman who has had a hysterectomy (surgical removal of the uterus), the health care team uses blood tests to find out if you have been through menopause.

Based on whether you have been through menopause, ASCO recommends the following:

**Tamoxifen**
- Can be considered as an option to reduce the risk of breast cancer, specifically ER-positive breast cancer for women who are age 35 or older
- Not recommended for women with a history of a blood clot, stroke, or who are immobilized (unable to move around) for a long time
- Not recommended for women who are pregnant or breastfeeding, or who may become pregnant

**Raloxifene**
- Can be considered as an option for women age 35 or older with a higher risk of breast cancer who have been through menopause
- Can be used longer than five years for women with osteoporosis, when lowering breast cancer risk is an added benefit of the drug
- Should not be used to lower breast cancer risk in women who have not been through menopause or who have a history of blood clots, stroke, or are immobilized for a long time

**Exemestane**
- Can be considered as an alternative to tamoxifen or raloxifene to lower breast cancer risk for women age 35 or older who have been through menopause
- Should not be used to lower breast cancer risk for women who have not been through menopause

**WHAT THIS MEANS FOR YOU**

Before considering treatment to reduce the risk of breast cancer, talk with your health care team about your breast cancer risk. Assessing your risk of breast cancer helps the doctor determine if these drugs can help reduce your risk. Because women taking a drug may experience side effects, it is important to talk with your doctor to learn about the risks and benefits of each treatment. It is also important to remember, that exemestane is not FDA-approved for breast cancer prevention, so it may not be easily available to you.

The drugs discussed in this guideline have been shown to reduce the risk of ER-positive invasive breast cancer, the most common type of breast cancer in women who have been through menopause. Before deciding whether to take drugs to lower your breast cancer risk, you may want to consider the following:

- How concerned you are about your risk of breast cancer
- Which side effects are you most concerned about
- How any side effects may affect your quality of life
- Availability of the drugs used to lower breast cancer risk

Talk with your doctor about these concerns and the benefits and risks of taking these drugs.
HELPFUL LINKS
Read the entire clinical practice guideline, as well as a discussion guide to help women talk with their doctors about the use of drugs to lower breast cancer risk at www.asco.org/guidelines/bcrr.

Guide to Breast Cancer
www.cancer.net/breast

Chemoprevention
www.cancer.net/prevention

ABOUT ASCO’S GUIDELINES
To help doctors give their patients the best possible care, ASCO asks its medical experts to develop evidence-based recommendations for specific areas of cancer care, called clinical practice guidelines. Due to the rapid flow of scientific information in oncology, new evidence may have emerged since the time a guideline or assessment was submitted for publication. As a result, guidelines and guideline summaries, like this one, may not reflect the most recent evidence. Because the treatment options for every patient are different, guidelines are voluntary and are not meant to replace your physician’s independent judgment. The decisions you and your doctor make will be based on your individual circumstances. These recommendations may not apply in the context of clinical trials.

The information in this patient guide is not intended as medical or legal advice, or as a substitute for consultation with a physician or other licensed health care provider. Patients with health-related questions should call or see their physician or other health care provider promptly and should not disregard professional medical advice, or delay seeking it, because of information encountered in this guide. The mention of any product, service, or treatment in this guide should not be construed as an ASCO endorsement. ASCO is not responsible for any injury or damage to persons or property arising out of or related to any use of this patient guide, or to any errors or omissions.

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