

# Menopause Hormone Therapy in Cancer Survivors

Jennifer Ducie, MD

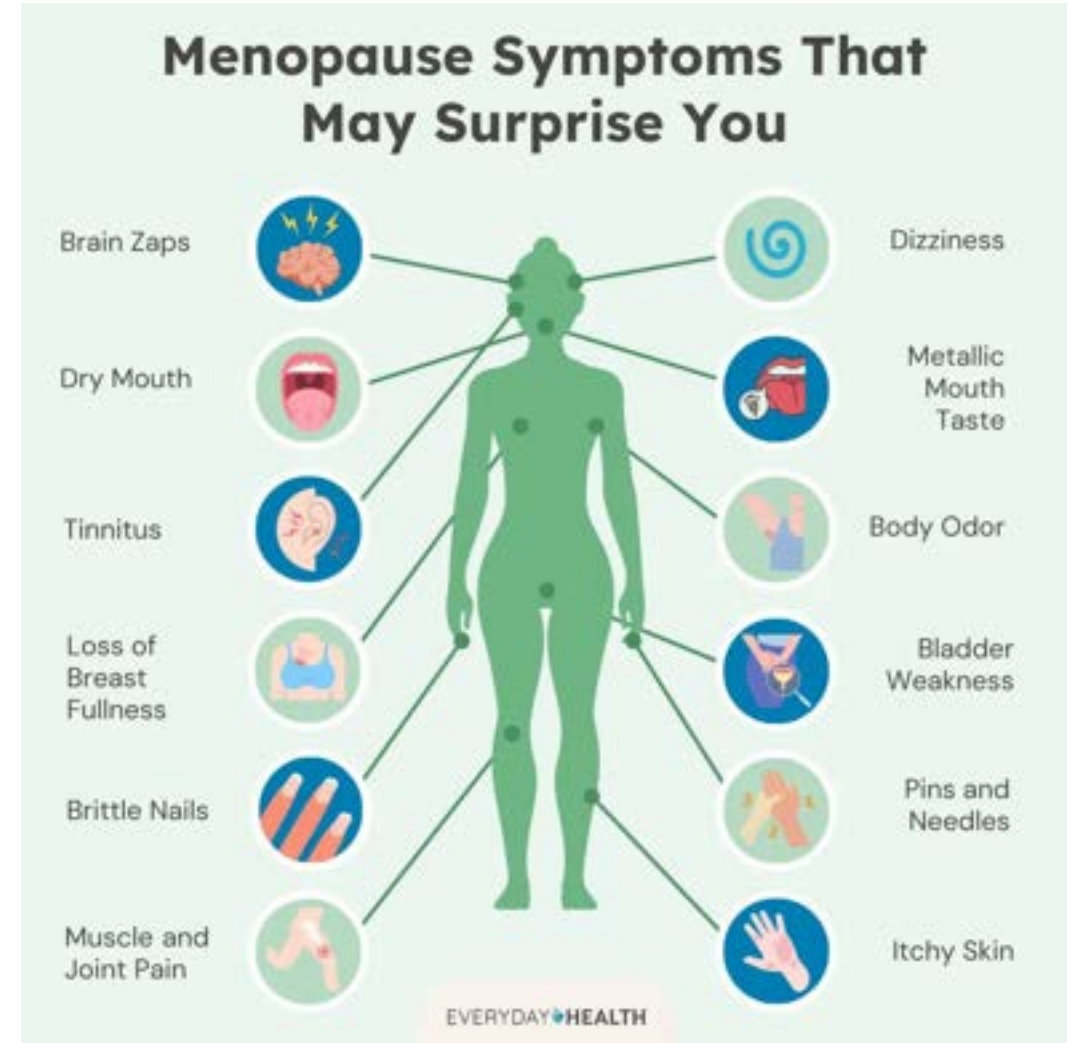
Gynecologic Oncology

Midwest Gyn Oncology, Nebraska Methodist Hospital

- I have no financial disclosures
- This is not medical advice. Please consult with your oncologist and personal physicians to see if menopause hormone therapy (MHT) may be appropriate for you.

# What is Menopause?

- Menopause is defined as cessation of menses for 12 months.
- Natural menopause, ~ 51yo
- Surgical menopause, immediate cessation of menses

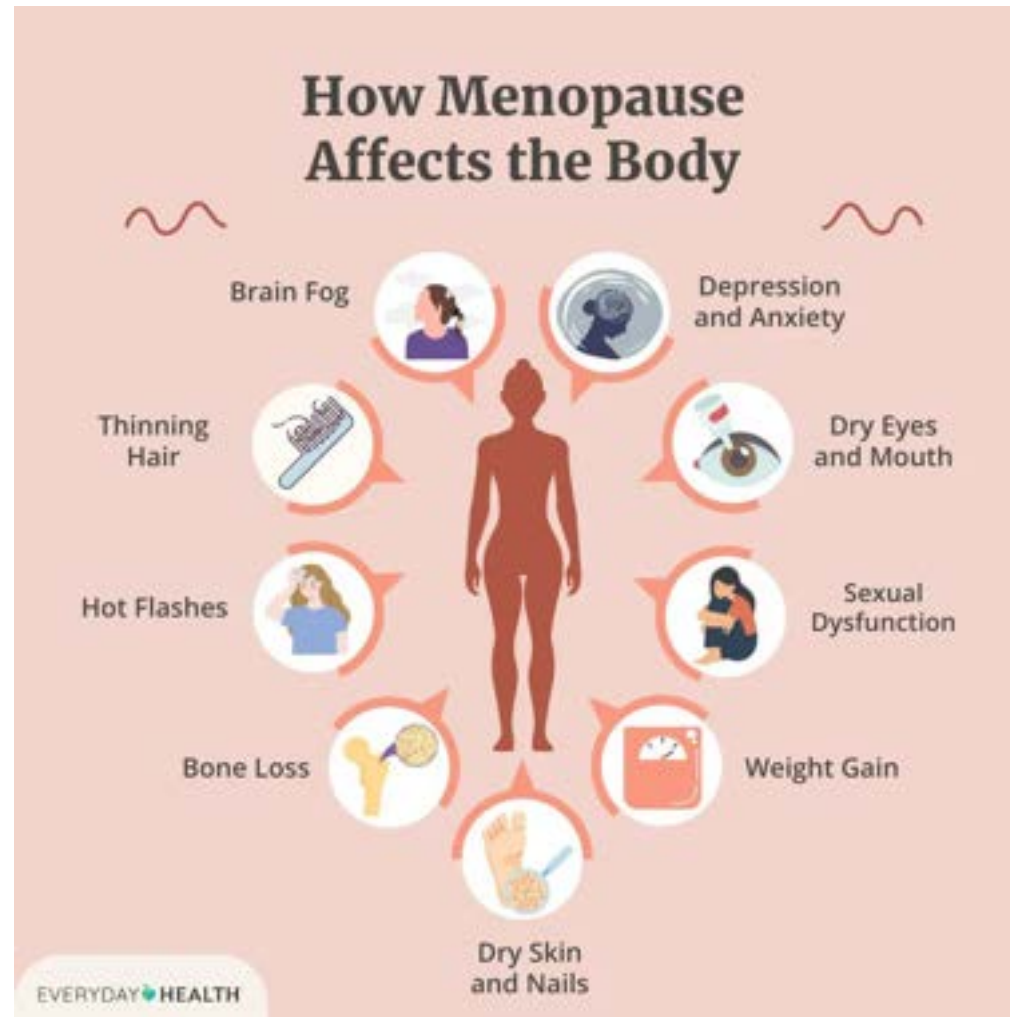


# How may you experience menopause?

Vasomotor symptoms:  
hot flashes and night  
sweats

Genitourinary syndrome of  
menopause:  
Vaginal dryness  
Pain with intercourse  
Atrophy

Sarcopenic obesity:  
Reduced muscle mass  
Increased visceral fat



Musculoskeletal  
syndrome of menopause

Cognitive change:  
Brain fog  
ADHD-like symptoms  
Anxiety  
Depression  
Dementia  
Parkinson's

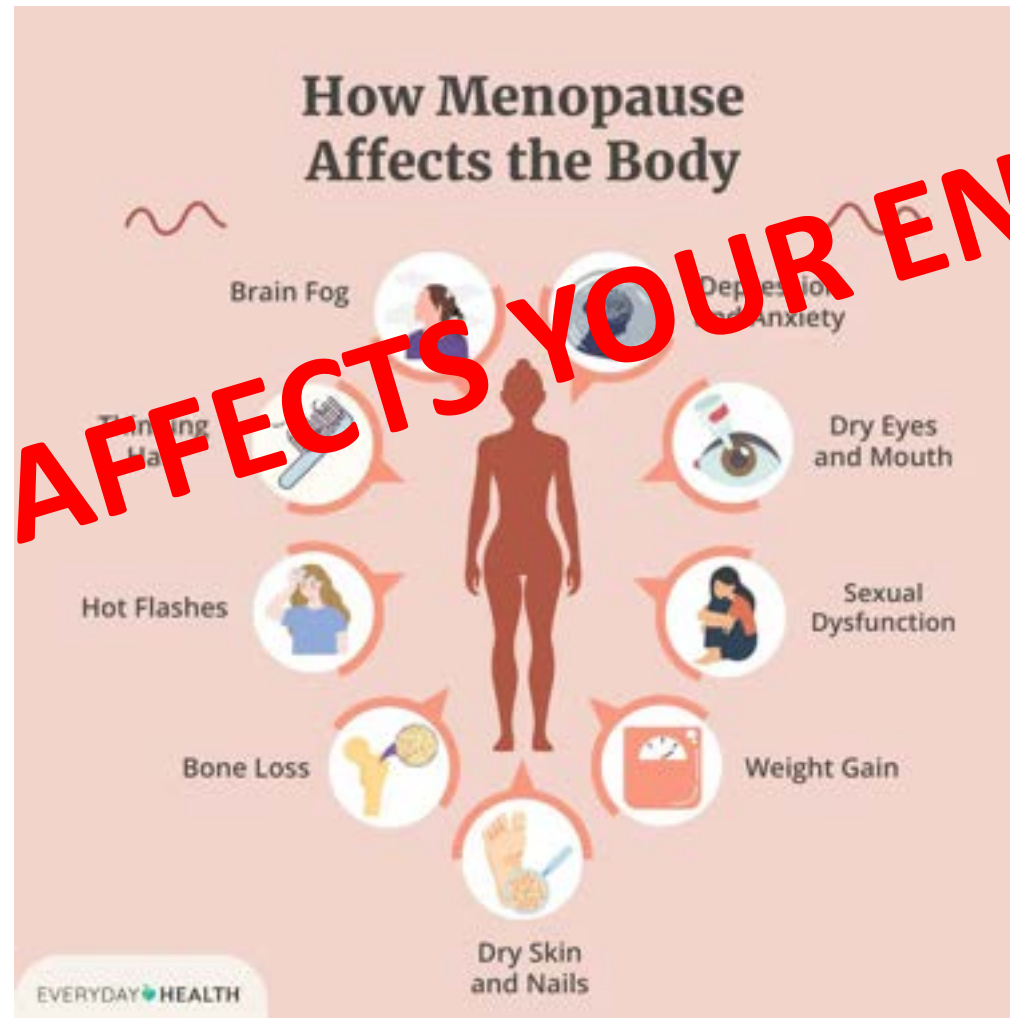
Metabolic syndrome:  
Insulin resistance  
High cholesterol and triglycerides  
High blood pressure  
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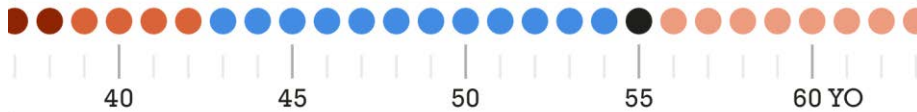
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# Menopause Timeline and Symptoms

Menopause is a natural process that usually happens when someone is in their 40s and 50s, but this timing can vary.

Estrogen production starts to drop

Very little to no estrogen



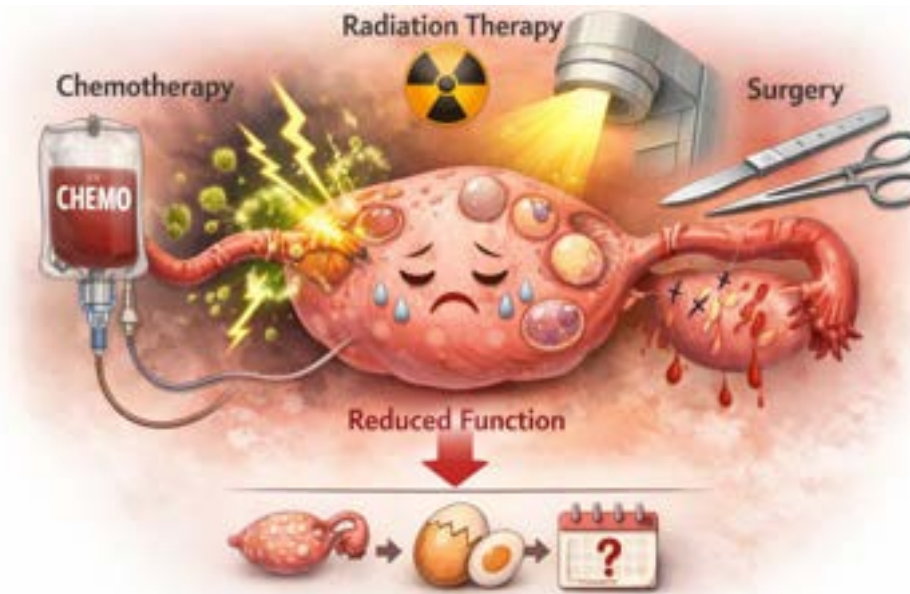
No matter when someone starts or finishes the transition, the general stages are the same.

PREMENOPAUSE	PERIMENOPAUSE	MENOPAUSE	POSTMENOPAUSE
Change in periods	A range of symptoms, including hot flashes, mood changes, and trouble sleeping	Menstrual periods completely stop, symptoms of perimenopause may continue	Menopause is complete, but some symptoms, like hot flashes, may continue

 GoodRx Health

- Natural menopause gradual transition
- Average age of menopause, ~52yo
- May experience perimenopause for 10 years before going through menopause

# Menopausal transition for Patients with Cancer



# Symptoms of Aromatase Inhibitors and SERMs

- Aromatase inhibitors – AIs
- SERMs – Tamoxifen (hot flashes in 80% of women)
- Side effects can mimic or worsen vasomotor symptoms of menopause, vaginal dryness, joint pain, muscle pain, decreased bone mineral density

# Potential detriment from estrogen deficiency and premature menopause

- Increased risk of heart disease and stroke
- Bone loss → osteopenia and osteoporosis
- Brain fog/ADHD symptoms
- Early dementia
- Parkinson's disease
- Increased overall mortality

# Managing symptoms of menopause

Smoking cessation

Limiting alcohol intake

Exercise (yoga)

Lifestyle modifications  
(dress in layers,  
use fan at night)

Weight loss

Menopause hormone therapy  
(MHT)

# How can MHT help?

- Approved for treatment of vasomotor symptoms (VMS) and genitourinary syndrome of menopause (GSM)
- Can reduce risk of osteoporosis
- May improve insomnia, anxiety, depression

# Women's Health Initiative (WHI) 2002

- Largest, randomized controlled trial of HT in women ages 50-79yo; enrolled 27K patients between 1993-1998 at 40 US centers
- In this study, only ONE route of administration (oral), one formulation of estrogen (conjugated equine estrogen [CEE] 0.625mg) and only one progestogen (medroxyprogesterone acetate [MPA] 2.5mg), with limited enrollment of women with bothersome VMS aged <60yo or who were fewer than 10 years from menopause onset
- **Did not include women with premature or early menopause**

# Women's Health Initiative 2002

- Messaging from professionals and media triggered a sensationalized response
- Resulted in major pivot away from prescribing MHT
- Data misinterpreted resulted in misguidance and fear about MHT



**HORMONE THERAPY**

FDA NEWS RELEASE

# HHS Advances Women's Health, Removes Misleading FDA Warnings on Hormone Replacement Therapy

**For Immediate Release:** November 10, 2025

The U.S. Department of Health and Human Services (HHS) today announced historic action to restore gold-standard science to women's health. After more than two decades of fear and misinformation surrounding hormone replacement therapy (HRT), the U.S. Food and Drug Administration (FDA) is initiating the removal of broad "black box" warnings from HRT products for menopause.

Health and Human Services Secretary Robert F. Kennedy Jr. and FDA Commissioner Marty Makary, M.D., M.P.H. made the announcement at a [press conference](#) at HHS with more than 200 people in attendance, including Second Lady of the United States Usha

# ASCO Statement: HHS Revision of Black Box Warning for Hormone Replacement Therapy and its Implications for Cancer Care

**ASCO** in Action  
News, Advocacy, and Analysis on Cancer Policy

Nov 13, 2025

On November 10, 2025, the Department of Health and Human Services announced that the Food and Drug Administration will begin to remove the "black box" warning language related to increased risks of cardiovascular disease, breast cancer, and probable dementia from hormone replacement therapy (HRT) products for menopause. The decision was based on a comprehensive review of the scientific data and expert panel consensus.

In response to the change and its potential implications in cancer care, ASCO issued the following statement:

"For many women without a history of cancer, this FDA change is intended to reduce fear and align with current data. For healthy women, particularly those under age 60 or within 10 years of menopause onset, the benefits of using systemic HRT for menopausal symptoms can outweigh the risks.

"ASCO cautions, however, that this labeling change does not apply to individuals with a history of estrogen-responsive cancers.

"Systemic hormone replacement therapy remains contraindicated for people who previously had breast cancer, particularly those with hormone receptor-positive disease, or other estrogen-responsive cancers (for example, certain gynecologic cancers), due to an increased risk of cancer recurrence. Low-dose vaginal estrogen remains a good option for breast cancer survivors whose genitourinary symptoms do not respond to non-hormonal treatments such as vaginal lubricants and moisturizers, after discussing the relative risks and benefits with their oncology professional.

# NAMS position statement 2022

- NAMS = North American Menopause Society
- MHT remains *most effective* treatment for VMS and GSM
- MHT can *prevent* bone loss and fracture
- Treatment should be individualized with periodic reevaluation of the benefits and risks of continuing therapy
- Start with lowest effective dose that provides symptom relief
- Appropriate dose of progestogen is added to provide endometrial protection

# Menopause hormone therapy

- What about in cancer survivors?
- What about for patients with hormone positive cancers?



# MHT in Cancer Survivors

# Cancer Survivorship

- According to NCCN, standard of survivorship care:
  1. Surveillance for cancer spread or recurrence, screening for other cancers
  2. **Monitoring long-term effects of cancer (psychosocial, cognitive, physical, and immunologic effects)**
  3. Prevention and detection of late effects of cancer and therapy
  4. Evaluation and management of cancer-related syndromes
  5. Coordination of care between PCPs and specialists to ensure all of survivor's health needs are met
  6. Planning for ongoing survivorship care

# Risks of hormone therapy

- Thrombosis/blood clot risk
  - Cancer patients at higher risk for development of PE/DVT
- Increased risk of stroke
- Increased risk of cancer
  - Recent data suggests estrogen can REDUCE risk of breast cancer

# Cautionary use

- Increased risk of VTE (blood clots)
  - Double the risk with ORAL estrogen
  - No increased risk with transdermal estrogen (patch or gel) or vaginal ring
  - Risk greater with increasing age, obesity, immobility, clotting disorders, and fracture

# Traditional hormone options

- Estrogen
  - Approved to treat VMS and GSM
  - Can prevent osteoporosis
- Progesterone/progestins
  - Primary purpose is to use in patients with a uterus to prevent development of endometrial hyperplasia and cancer

# Informed consent is KEY

- After shared decision making, review of the risks and benefits of a certain treatment, providers \*may\* prescribe hormone therapy to select patients.
- Ultimately, cancer care is meant to cure and extend life, while preserving quality of life.

Treatment options for  
Genitourinary syndrome of  
Menopause (GSM)

# Treatment options for GSM

- First-line therapy: Non-hormonal lubricants and moisturizers
- Hormonal options
  - Creams
  - Suppository
  - Ring
- Pelvic floor PT
- Laser therapy

Table 1. Nonhormonal and Hormonal Treatment Options		
Formulation	Composition	Dosages
Nonhormonal options		
Lubricants	Water-, silicone-, and polycarboxophil-based products	See product labeling
Moisturizers	Hyaluronic acid Polyacrylic acid Polycarboxophil-based vaginal moisturizer	5 mg daily for 2 weeks, then 3–5 times per week 3 g daily 2.5 g 3 times/week
Vaginal suppositories	Vitamin E Vitamin D	30–200 international units 1,000 international units
Lidocaine	4% aqueous lidocaine	Fully saturated cotton ball applied to the vulvar vestibule for 3 minutes
Hormonal options		
Vaginal insert	Prasterone*	One 6.5-mg vaginal insert once daily
Vaginal cream	17 $\beta$ -estradiol <sup>†</sup>	The usual dosage range is 1 to 4 g (marked on the applicator) daily for 1 or 2 weeks, then gradually reduced to one-half initial dosage for a similar period; a maintenance dosage of 1 g, 1 to 3 times a week, may be used after restoration of the vaginal mucosa has been achieved <sup>‡</sup>
Vaginal cream	Conjugated equine estrogen	<ul style="list-style-type: none"> <li>• Evidence-based regimen: twice weekly administration of 0.5 g intravaginally (eg, Monday and Thursday) for treatment of moderate-to-severe dyspareunia</li> <li>• Dosage regimens of 1 g every night for 2 weeks, then twice a week or 0.5 g twice a week are commonly used<sup>‡§</sup></li> </ul>
Vaginal ring	17 $\beta$ -estradiol	7.5 micrograms/day for 90 days
Vaginal tablet or insert	Estradiol hemihydrate	<ul style="list-style-type: none"> <li>• 10 micrograms/day for 2 weeks, then 10 micrograms/day 2 times a week</li> <li>• A vaginal insert containing 4 micrograms is available, although not used in included studies</li> </ul>
Vaginal cream	Testosterone	<ul style="list-style-type: none"> <li>• 300 micrograms or 150 micrograms applied daily for 28 days</li> <li>• 300 micrograms or 150 micrograms applied daily for 2 weeks, then 3 times a week</li> </ul>
<p>*The product label contains the following warning and precaution for those with a current or past history of breast cancer: "Estrogen is a metabolite of prasterone. Use of exogenous estrogen is contraindicated in women with a known or suspected history of breast cancer. [It] has not been studied in women with a history of breast cancer." Additional data have been published on this population since the U.S. Food and Drug Administration approval of this medication.</p> <p><sup>†</sup>Known, suspected, or history of breast cancer is listed as a contraindication in the product label.</p> <p><sup>‡</sup>U.S. Food and Drug Administration–approved dosages of conjugated estrogen and estradiol creams may be higher than dosages commonly used in clinical practice.</p> <p><sup>§</sup>Study protocol: cyclic administration of 0.5 g intravaginally (daily for 21 days then off for 7 days) for treatment of moderate-to-severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.</p>		

Treatment of Urogenital Symptoms in Individuals with a history of estrogen-dependent breast cancer. ACOG Committee on Clinical Consensus, Number 2, American College of Obstetricians and Gynecologists. Obstet Gynecol. 2021;138:950-60.

# Low-dose topical vaginal estrogen

- Highly effective in relieving symptoms of GSM when compared to placebo or non-hormonal options
- May reduce risk of recurrent UTIs, improve pain with intercourse, reduce dryness
- Studies addressing safety of use in breast cancer lacking, though 7 studies with 4000 breast cancer patients did not show increased recurrence



**Safe for patients  
with personal  
history of breast  
cancer and  
gynecologic  
cancers**

# Topical Estradiol options

- Vaginal estradiol cream 0.01% - 1g twice weekly
- Estradiol vaginal inserts- 1 insert twice weekly
- Vaginal DHEA – nightly for 14 nights, then 2-3x per week
- \* Vaginal estradiol preferred to DHEA in patients with history of breast cancer.

# Vaginal estrogen in breast cancer

- Localized, low-dose vaginal estradiol (0.01% cream, 0.25 gm 2-5x/week), 10ug tablets or 10ug suppositories (daily for 2 weeks then 2-5 x/week), or ring (7.5ug/d) have been evaluated in 9 studies in breast cancer survivors.
- 2025 systematic review and meta-analysis across 8 trials (including women on AIs), showed no significant increase in breast cancer recurrence or mortality.

# Ospemifene

- Selective estrogen receptor modulator (SERM)
  - Estrogen agonist on vaginal tissue and bone
  - Antagonist on breast tissue
- Approved by FDA for treatment of **postmenopausal vulvovaginal atrophy, 60mg by mouth daily**
  - FDA approval includes warning for use in patients with a history of breast cancer and states “it should not be used in women with known or suspected breast cancer” → controversial
  - In Europe, approved for use of women with breast cancer who have completed therapy

# Prasterone

- Vaginal dehydroepiandrosterone (DHEA) 6.5mg daily
  - May help with dyspareunia and improve vaginal tissue health
  - Approved by FDA for treatment of moderate-to-severe pain with intercourse (dyspareunia) due to menopause/vaginal atrophy
  - May reduce UTIs
  - DHEA → androstenedione → estrogen
  - RCT: 464 women with history of breast and gyn cancers compared both 6.5mg and 3.25mg vaginal DHEA with plain moisturizer. Both arms reported improvement in dryness or dyspareunia. Higher dose DHEA arm reported better sexual health outcomes.

# MHT for Gynecologic Cancer Survivors

# MHT in Gynecologic Cancer Survivors (and Pre-vivors)

- Limited data
- Likely safe in carefully selected patients with early-stage endometrial and ovarian cancers, vaginal/vulvar/cervical cancers <sup>1,2</sup>
- Avoid in patients with hormonally driven tumors<sup>3</sup>
  - Uterine sarcomas
  - Low-grade serous ovarian cancer
  - ? Endometrioid type ovarian cancer

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2. Gorman M and Shih K. Updates in Hormone Replacement Therapy for Survivors of Gynecologic Cancers. *Curr Treat Options Oncol.* 2025 Mar 5;26(3):179-186.

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# MHT and endometrial cancer

- Prospective study of over 1200 pts with early stage endometrial cancer who received ET vs placebo after surgical staging did not show increased harm.
  - \*\*Study incomplete and closed early due to release of WHI.
  - 2.3% of patients who received ET developed recurrence vs 1.9% in placebo arm<sup>1</sup>
- Meta-analysis<sup>2</sup> and Cochrane review<sup>3</sup> conclude that HRT is safe for patients with early-stage endometrial cancer
- Safety of MHT has not been study in patients with advanced disease and is not recommended.

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2. Shim SH, LEE SJ, Kim SN. Effects of hormone replacement therapy on the rate of recurrence in endometrial cancer survivors: A meta-analysis. Eur J Cancer. 2014;50(9): 1628-37.  
3. Edey KA, Rundle S, Hickey M. Hormone replacement therapy for women previously treated for endometrial cancer. Cochrane Database Syst Rev. 2018;5:CD008830.

# MHT and ovarian cancer

- Prospective study of 799 women in Sweden with EOC or borderline ovarian tumors; no difference in survival if patients used HRT before or during diagnosis<sup>1</sup>.
- Meta-analysis<sup>2</sup> of 2 RCTs and 4 cohort studies suggested that MHT has a favorable impact on OS in patients with EOC and not associated with increased risk of recurrence.
- South Korean study<sup>3</sup> showed that postop HRT improved overall survival in patients with EOC. Impact of HRT on survival increased with time and treatment duration.

1. Eeles RA, et al. Adjuvant hormone therapy may improve survival in epithelial ovarian cancer. Results of the AHT randomized trial. *J Clin Oncol*. 2015;33(35):4138-44.

2. Li D, Ding CY, Qiu LH, Postoperative hormone replacement therapy for epithelial ovarian cancer patients: A systematic review and meta-analysis. *Gynecol Oncol*. 2015;139(2): 355-62.

3. Ji E, Kim K, Lee B, et al. Postoperative hormone replacement therapy and survival in women with ovarian cancer *Cancers (Basel)*. 2022;14(13):3090.

# HRT contraindicated in these ovarian cancer types

- Low-grade serous ovarian cancer
- Granulosa-cell tumors
- Endometrioid ovarian cancers (especially ER+, advanced disease)

# MHT in Cervix Cancer

- Safe, no contraindication, for most cervical cancers
- Ovarian conservation recommended in squamous cell carcinomas in premenopausal patients
- Small RCT looking at ET or EPT vs placebo in pts with early-stage cervix cancer treated with surgery or RT, no difference in 5-year disease free or overall survival
- Use with caution in adenocarcinomas of cervix
- Combination therapy recommended for patients with uterus

# MHT in vaginal/vulvar cancers

- No contraindication for patients with squamous cell carcinomas of vagina and vulva (typically HPV-related cancers)
- No data available for adenocarcinomas of vagina and vulva

# MHT in Breast Cancer Survivors

# MHT and breast cancer

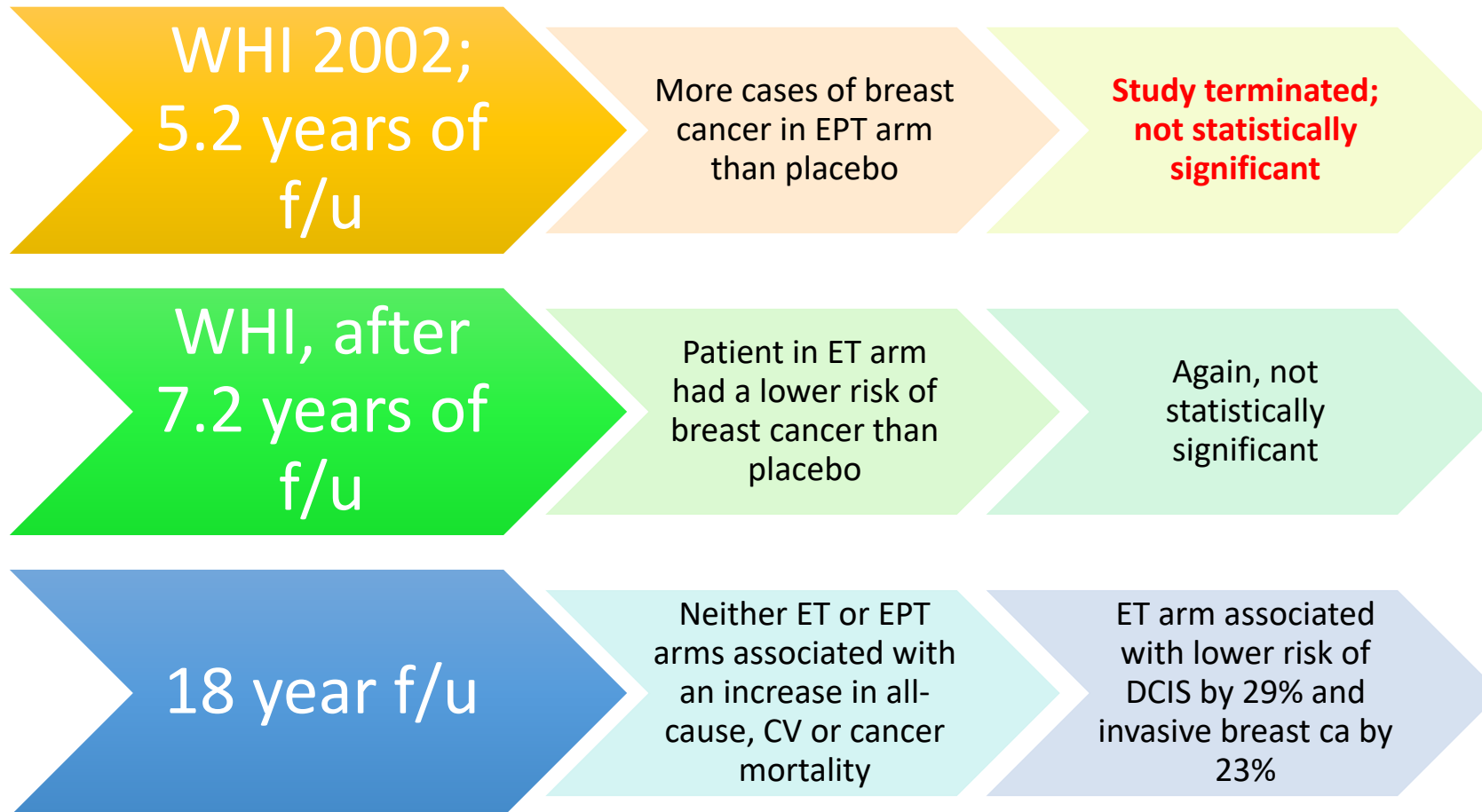
- Is there a subset of patients with a history of breast cancer who may be candidates for systemic hormone therapy?
- Or, should we continue to tell all patients with breast cancer that there is a hard stop on hormone therapy?
- Bosserman and Dizon<sup>1</sup> encourage providers to consider *personalizing therapy*

# MHT in Breast Cancer Survivors

- As with gyn cancers, limited data and more controversial.
- ASCO reminds us and reiterates that hormone therapy remains contraindicated in patients with hormone-receptor positive breast cancer.
- But, what does contemporary data say? And, what about survivorship and quality of life?

# First line: Non-hormonal options

- Fezolinetant (neurokinin B receptor antagonists)– non-hormonal daily oral medication to reduce VMS
- SSRIs and SNRIs
  - Paroxetine (cannot use if taking Tamoxifen)
  - Venlafaxine and citalopram preferred
  - Can be used safely in patients using AIs
- Gabapentin nightly (300 --> 900mg)



Interestingly, among patients in placebo groups, those who had used MHT in the past had lower breast cancer risks than those who never used MHT; and when they compared patients in EPT arm vs never users of MHT, no increased risk of breast cancer was identified.

Writing Group for the Women's Health Initiative Investigators. Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principal Results From the Women's Health Initiative Randomized Controlled Trial. *JAMA*. 2002;288(3):321–333. doi:10.1001/jama.288.3.321

Manson JE, Aragaki AK, Rossouw JE, et al. Menopausal Hormone Therapy and Long-term All-Cause and Cause-Specific Mortality: The Women's Health Initiative Randomized Trials. *JAMA*. 2017;318(10):927–938. doi:10.1001/jama.2017.11217

- 2024 Meta-analysis of 10 RCTs demonstrated that CEE-alone (ET) MHT significantly reduces incidence of breast cancer vs placebo (overall relative risk of 0.77, 95% CI 0.65-0.91)<sup>1</sup>

# Choose MHT carefully

- Use of synthetic progestogens have been shown to greater breast cancer risk
- Micronized progesterone has not been shown to increase breast cancer risk with  $\leq$  years of use (need more data  $>5$  years of use)
- Transdermal estradiol: No detectable increased risk of breast CA

# Systemic MHT in breast cancer survivors

- HABITS – RCT:
  - 434 Scandinavian women with stage 0-2 breast cancer, enrolled regardless of tumor HR status and randomly assigned to clinician's choice systemic MHT or not. Median f/u 2.1 years, 26 women in MHT group and 7 in control group had new breast cancer event (HR 3.5 [95% CI, 1.5 to 8.1]), seen specifically in women with HR-positive breast cancer. Trial terminated. After 4 year f/u, no difference in cancer mortality. Study heavily criticized.
- Stockholm – RCT: 378 women with breast cancer randomly assigned, irrespective of HR status, to MHT with ET or EPT; 52% took tamoxifen. Did not report a statistically significant difference in recurrence. No reported difference in overall mortality or breast cancer mortality.
- Smaller prospective cohort study from MDACC, 56 took CEE (ET) with median f/u 5.9 years, recurrence risk not elevated compared to patients who did not take HT, with numerically fewer breast cancer recurrence events.

## DCIS

ET unlikely to increase risk of 2<sup>nd</sup> breast cancer

MHT likely to increase risk of progression and relapse if residual ER+ disease

## HR negative breast cancer

ET only unlikely to increase risk of 2<sup>nd</sup> breast cancer

EPT (synthetic P) likely to increase risk of 2<sup>nd</sup> breast cancer; risk lower if P bioidentical

## HR positive breast cancer

EPT likely to increase relapse, esp within 5-10yrs of dx

Can be used to treat sx in women with a high level of caution

# Potential option...The PROMISE Study 2025

- Tissue selective estrogen complex (TSEC)
- Estrogen (CE) and bazedoxifene (BZA) - SERM
  - FDA approved MHT designed to **treat moderate-severe VMS** and **prevent osteoporosis**
  - CE treat menopausal symptoms, while BZA acts as estrogen agonist/antagonist and protects the endometrium/uterus
  - Single tablet, by mouth, daily
- Associated with small increase in risk of VTE, stroke, and MI

# The PROMISE Study 2025

- Multi-center phase 2 randomized clinical trial studied CE-BZA in 141 pts with ER+ DCIS
- Drug significantly reduced breast cell proliferation (Ki-67) and treats menopausal symptoms
- May offer a safer hormonal alternative to treat menopausal sx in women with high breast cancer risk
- More investigation required to determine if indeed option for breast cancer prevention

# Conclusions

- Menopause includes a constellation of symptoms that warrant therapy and is an integral part of cancer survivorship.
- Vaginal estrogen is safe for ALL patients.
- Hormone therapy after a cancer diagnosis is always worth a discussion.
- Shared decision making is essential to provide the best care to each individual patient.
- More high-quality randomized trials are needed.

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