NORTH DAKOTA ACADEMY OF FAMILY MEDICINE • 2026 CME SESSION

Hormone Therapy in 2026

From the WHI Panic to the Precision Era: A Practical Update for Family Medicine

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SESSION ROADMAP

Today's Objectives

Re-read the WHI
Separate the 2002 headlines from the age-stratified data those headlines were built on.

Trace the evidence arc
Follow the science from the 2002 alarm to the FDA's 2025–26 label reversal.

Compare estrogen options
Oral, transdermal patch, gel, spray, and vaginal formulations — patch-to-patch included.

Compare progestogens
Micronized progesterone vs. synthetic progestins: doses, regimens, and safety signals.

Apply the newest data
Cardiovascular, breast cancer mortality, cognitive, and bone findings since HT's return.

Get it covered
ICD-10 / CPT coding tactics and documentation that support visit and prescription coverage.

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PART 1 OF 6

The WHI: What Actually Happened

Revisiting the trial that reshaped a generation of practice — on its own numbers.

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THE TRIAL

Two Randomized Trials, One Umbrella

The Women's Health Initiative enrolled 161,808 women (1993–1998) to study chronic disease prevention in postmenopausal women. Its hormone therapy component held **two separate randomized, placebo-controlled trials** — and they produced two different stories.

Estrogen + Progestin (E+P)	Estrogen-Alone (CEE)
16,608 women	**10,739 women**
Intact uterus — CEE 0.625 mg + MPA 2.5 mg vs. placebo	Prior hysterectomy — CEE 0.625 mg vs. placebo
Halted early, July 2002	*Continued to planned close, 2004*

Mean age at enrollment: 63 — more than a decade past the median U.S. menopause age of 51.

JAMA • JULY 17, 2002
"Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women"
WHI Writing Group. 2002;288(3):321–333

JAMA • APRIL 14, 2004
"Effects of Conjugated Equine Estrogen in Postmenopausal Women With Hysterectomy"
WHI Steering Committee. 2004;291(14):1701–1712

Both trials tested one formulation, one dose, one route: oral CEE, 0.625 mg/day.

Writing Group for the WHI Investigators. JAMA. 2002;288(3):321–333. • WHI Steering Committee. JAMA. 2004;291(14):1701–1712.

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THE BASHING OF ESTROGEN

July 2002: Relative Risk Made the Headlines

WIRE COVERAGE • JULY 2002
"HRT Increases Cancer Risk"
Headline as widely reported; paraphrased

PRESS COVERAGE • JULY 10, 2002
Reported: 41% more strokes, 29% more heart attacks, 26% more breast cancer
Relative-risk figures, reported without absolute context

NIH PRESS CONFERENCE • JULY 9, 2002
E+P arm stopped early: data safety board calls a halt
Trial closed ~3 years ahead of schedule

What the trial actually measured (E+P vs. placebo, mean follow-up 5.2 years):

Outcome	Hazard Ratio (95% CI)	What it meant in absolute terms
Invasive breast cancer	1.26 (1.00–1.59)	A few additional cases per 10,000 women per year
Stroke	1.41 (1.07–1.85)	A few additional cases per 10,000 women per year
Pulmonary embolism	2.13 (1.39–3.25)	Roughly doubled a small baseline rate
Hip fracture	0.66 (0.45–0.98)	Fewer fractures with E+P — a benefit, not a risk
Colorectal cancer	0.63 (0.43–0.92)	Fewer cases with E+P — also a benefit

Every headline number was a relative risk on a rare event. The absolute risk difference for most outcomes was in the single digits per 10,000 women per year.

Rossouw JE, et al. JAMA. 2002;288(3):321–333.

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WHY THIS MATTERS NOW

A 22-Percent Swing in Practice Patterns

Menopausal hormone therapy (MHT) use among U.S. postmenopausal women, 1999–2020

26.9%
of postmenopausal women using MHT — 1999–2000

4.7%
by 2020 — the low point, largely unrecovered since

- One randomized trial arm, halted early in 2002, drove a two-decade retreat from a therapy most postmenopausal women could safely use.
- The steepest declines were in the women most likely to benefit: those 52 to <65 and within the early postmenopausal window.
- About 1.3 million U.S. women transition through menopause every year — roughly 80% report symptoms, severe in about 1 in 3.

The question for this hour: what changed — in the data, and now in the label?

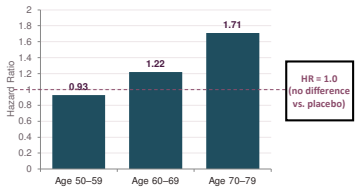
Yang Z, et al. JAMA Health Forum. 2024. • ObG Project, 2024.

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POST-ANALYSIS — BY DECADE

The Risk Depended Heavily on When Therapy Started

Coronary heart disease hazard ratio, E+P vs. placebo, by age at randomization



- Women randomized in their 50s showed no significant increase in CHD risk — the point estimate trended protective.
- Risk rose steadily with age at initiation; women started in their 70s drove most of the cardiovascular signal.
- The trend across age strata was statistically significant (p for trend = 0.02).
- This single figure became the foundation of the "timing" or "window" hypothesis discussed later in this talk.

Mean age at WHI enrollment was 63. The trial was designed and powered around an older population — not the newly menopausal women most likely to be prescribed HT in practice.

Rossouw JE, Manson JE, et al. JAMA. 2007;297(13):1465–1477 (age-stratified reanalysis).

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THE OTHER TRIAL

Estrogen-Alone Told a Different Story Entirely

In women with a prior hysterectomy, CEE alone **never showed the overall breast cancer or CHD signal** seen with E+P. And in the youngest enrollees, the long-term data looked favorable.

76
women age 50–59 randomized to CEE, per 1 fewer myocardial infarction over 13-year cumulative follow-up (NNT)

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women age 50–59 randomized to CEE, per 1 fewer global index event (CHD, breast cancer, stroke, fracture, or death) over 13 years (NNT)

–23%
relative reduction in invasive breast cancer incidence with CEE alone at 19-year follow-up

Interpretive caution: these age-band findings come from subgroup and long-term follow-up analyses, not the trial's original primary endpoint — hypothesis-generating, not a new RCT.

INTERNATIONAL JOURNAL OF ENDOCRINOLOGY • 2015
"A Reappraisal of the WHI Estrogen-Alone Trial: Long-Term Outcomes in Women 50–59 Years of Age"
Roehm E. 2015;2015:713295

The lesson: "HRT" was never one therapy. Estrogen-alone and estrogen-plus-progestin behaved differently — and still do.

Roehm E. Int J Endocrinol. 2015;2015:713295. • WHI Steering Committee. JAMA. 2004;291(14):1701–1712.

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POST-TALK ANALYSIS — THE LONG VIEW

20-Year Follow-Up: Breast Cancer Diverged by Regimen

JAMA • JULY 28, 2020
"Association of Menopausal Hormone Therapy With Breast Cancer Incidence and Mortality: 20-Year WHI Follow-Up"
Chlebowski RT, et al. 2020;324(4):369–380

	Estrogen alone (CEE)	Estrogen + progestin
Breast cancer incidence	↓ 23% vs. placebo	↑ 29% vs. placebo
Breast cancer mortality	↓ ~40% (HR 0.60)	No significant difference
Durability	Effect persisted >10 yrs after stopping	Effect persisted >10 yrs after stopping

In absolute terms: 30 breast cancer deaths among CEE-alone users vs. 46 among placebo users (annualized 0.031% vs. 0.046%) across the two WHI trial cohorts.

The lead investigator described this as the first pharmacologic intervention on record shown to significantly lower breast cancer deaths — not just incidence.
— Rowan T. Chlebowski, MD, PhD, lead investigator, paraphrased

Chlebowski RT, et al. JAMA. 2020;324(4):369–380.

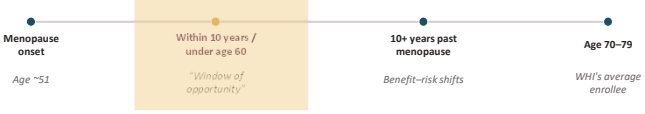
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THE SYNTHESIS

The Timing (Window) Hypothesis

Vascular biology gives this a mechanism: estrogen appears vasoprotective in healthy arteries, but may destabilize existing atherosclerotic plaque.



Favorable window
Initiation < 10 years from menopause or before age 60: vasomotor relief, bone protection, and neutral-to-favorable cardiovascular and mortality signals in multiple analyses.

Later initiation
Starting well past this window — as most WHI enrollees did — is where the cardiovascular and stroke signal concentrates.

Endorsed by NAMS, ACOG, and — as of late 2025 — the FDA's own label language, discussed next.

Clarkson TB, et al. Menopause. 2013;20(3):342–353. • Manson JE, et al. JAMA. 2013;310(13):1353–1368.

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Mortality: no long-term signal of overall harm

18-year cumulative follow-up

27.1% vs 27.6%

MHT vs placebo • HR 0.99 (95% CI 0.94–1.03)

- **NO** significant increase in ***all-cause mortality***
- **NO** significant increase in ***cardiovascular mortality***
- **NO** significant increase in ***total cancer mortality***

Manson JE et al. JAMA. 2017;318:927–938.

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Long follow-up changed the conversation

JAMA | 2017
MHT and 18-year all-cause & cause-specific mortality

JAMA | 2020
20-year breast cancer incidence & mortality after WHI randomization

JAMA | 2024
WHI randomized trials and clinical practice: a review

Manson et al. JAMA 2017; Chlebowski et al. JAMA 2020; Manson et al. JAMA 2024.

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WHI: what was actually studied

- ***16,608 women with a uterus***: CEE 0.625 mg + MPA 2.5 mg daily vs placebo
- ***10,739 women after hysterectomy***: CEE 0.625 mg daily vs placebo
- ***Age 50–79***; mean baseline age ≈63 years—many were well beyond the menopause transition
- ***Primary purpose***: chronic disease prevention, not treatment of a typical newly symptomatic 51-year-old
- ***Oral*** *conjugated equine estrogen ± medroxyprogesterone acetate*—not transdermal 17β-estradiol + micronized progesterone

Mean age = 63

Oral CEE

MPA in uterus arm

Prevention trial

Not "all HRT"

WHI Writing Group. JAMA. 2002;288:321–333; Manson et al. JAMA. 2024;331:1748–1760.

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PART 2 OF 6

The Return of Estrogen: 2025–2026

How two decades of reanalysis became a formal FDA label change.

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THE REVERSAL BEGINS

November 10, 2025: FDA Moves to Remove the Black Box

FDA / HHS • NOV 10, 2025
HHS Advances Women's Health, Removes Misleading FDA Warnings on Hormone Replacement Therapy
Press announcement, HHS & FDA

STROKE • AUG 21, 2025
Cardiovascular reanalysis in ~57,000 postmenopausal women informs the FDA review
Cited in the FDA's evidence review

NBC NEWS • NOV 10, 2025
"Hormone Replacement Therapy Will No Longer Carry a Warning Label, FDA Says"
National coverage of the announcement

- The FDA initiated removal of the broad boxed ("black box") warning from hormone therapy products containing estrogen — warnings the agency itself called based on outdated science.
- Boxed-warning language specific to cardiovascular disease, breast cancer, and "probable dementia" was targeted for removal.
- The endometrial cancer boxed warning remains for unopposed systemic estrogen — the rationale for progestogen co-therapy hasn't changed.
- New labeling was directed to reflect age-specific guidance: benefit is favored when therapy starts within 10 years of menopause onset.

FDA/HHS News Release, Nov 10, 2025. • Harvard Health Publishing, Nov 2025 (Stroke, Aug 21, 2025 analysis).

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IMPRESSIVE DATA SINCE THE RETURN — 1 OF 3

Cardiovascular Outcomes & Mortality

A 7-million-woman Medicare claims analysis

Using 13 years of CMS Part D claims (2007–2019), a retrospective study followed **more than 7 million women over age 65** — large enough to examine dose, route, and formulation in ways the original WHI trials could not. Estrogen-only therapy use beyond 65 was associated with meaningful reductions in mortality, several cancers, cardiac conditions, and dementia diagnoses.

Read this as high-quality observational data, not a randomized trial — it complements, but doesn't replace, the WHI RCT evidence.

A large reanalysis, published in Stroke (Aug 2025), likewise informed the FDA's decision to remove cardiovascular language from the boxed warning — evidence the agency itself cited as outdated for many current users.

Bottom line for counseling: in women who start within the favorable window, current data do not support treating cardiovascular risk as an automatic reason to withhold therapy.

Baik SH, et al. CMS VRDC retrospective study (medRxiv preprint). • Stroke, Aug 21, 2025, cited via Harvard Health, Nov 2025.

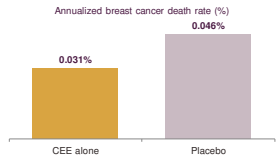
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IMPRESSIVE DATA SINCE THE RETURN — 2 OF 3

The Breast Cancer Mortality Signal Holds Up

Estrogen-alone: still the only pharmacologic intervention shown to lower breast cancer death



–23% breast cancer incidence with CEE alone vs. placebo (19-yr follow-up)

–40% relative reduction in breast cancer mortality with CEE alone (HR 0.60)

>10 yrs durability of the mortality benefit after therapy was stopped

This is the estrogen-alone arm specifically — women with a prior hysterectomy. It does not generalize to combined estrogen + progestin therapy.

Chlebowski RT, et al. JAMA. 2020;324(4):369–380 (20-year WHI follow-up).

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IMPRESSIVE DATA SINCE THE RETURN — 3 OF 3

Cognition and Bone: Promising, With Nuance

Cognition

Two out of every three Alzheimer's cases in the U.S. occur in women, and researchers are examining a possible **critical window** for neuroprotective estrogen effects around the menopause transition.

Counterpoint: a rigorous 2025 umbrella review (2000–2025 primary studies) found no significant effect of MHT on dementia risk in either direction — evidence expected to inform upcoming WHO guidance.

Takeaway: promising mechanism, genuinely mixed evidence — don't prescribe HT for cognitive protection alone.

Bone health

A 2025 systematic review comparing HRT with weight-bearing exercise found **greater improvements in bone mineral density with HRT** than with exercise therapy alone, plus reduced fracture risk at the hip and vertebrae.

This reinforces decades of consistent WHI-era data: HT reliably reduces hip and vertebral fracture risk — among its most durable, least-disputed benefits.

Bone protection remains an evidence-based reason to consider HT in appropriately selected younger postmenopausal women.

NBC News, Nov 27, 2025 (cognition). • Pharmacy Times, Feb 2026 (umbrella review). • Systematic review, PMC, 2025 (bone).

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SYNTHESIS

2002 vs. 2026: The Same Data, a Different Read

2002

Relative risk, all ages pooled, media-driven

- Headlines led with ***relative risk*** on rare events
- ***All ages (50–79)*** analyzed as one pooled group
- ***Class-wide boxed warning*** applied to every product
- ***MHT use fell from 26.9% to 4.7%*** of postmenopausal women

2026

Absolute risk, age-stratified, FDA-endorsed

- ***Absolute risk and NNT*** reported alongside relative risk
- Age-stratified: ***favorable window under 60 / within 10 years***
- Boxed warnings for ***CV disease, breast cancer, dementia removed***
- ***Labels individualizing*** and moving toward age-specific guidance

See prior slides for full citations.

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PART 3 OF 6

Choosing a Regimen: Estrogen

Route and formulation now matter as much as the decision to treat.

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FORMULATIONS

Estrogen Comes in Five Practical Forms

Oral

Tablets (e.g., oral estradiol, conjugated equine estrogens). Convenient, well-studied — undergoes hepatic first-pass metabolism.

Transdermal patch

Once- or twice-weekly patches deliver steady-state estradiol, bypassing first-pass metabolism.

Gel / spray

Daily topical estradiol gel or spray; dose-titratable, transdermal absorption profile.

Vaginal ring / tablet

Systemic (higher-dose ring) or low-dose local formulations for genitourinary symptoms.

Low-dose vaginal cream

Local therapy for genitourinary syndrome of menopause; minimal systemic absorption.

All are legitimate first-line options for a symptomatic, appropriately screened candidate. The choice is about risk profile, preference, and cost — not a hierarchy of efficacy for vasomotor symptoms.

ACOG Practice Bulletin; NAMS 2022 Hormone Therapy Position Statement.

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ROUTE MATTERS

Why Transdermal Is Often the First Reach

	Oral estrogen	Transdermal estrogen
Hepatic first-pass metabolism	Yes — increases hepatic protein synthesis (clotting factors, SHBG, triglycerides)	Bypassed — delivered directly to systemic circulation
Observational VTE / stroke signal	Higher, relative to transdermal	Lower, in most observational comparisons
Typical use case	Cost-effective, simple dosing; fine for average-risk candidates	Preferred when VTE risk factors, migraine with aura, hypertriglyceridemia, or smoking are present
Serum level pattern	Peak-trough with daily dosing	Steadier state between changes

This is an observational, mechanism-supported signal, not a randomized head-to-head comparison from WHI — the original trials tested oral CEE only.

Clinical pearl: for a patient with cardiometabolic or thrombotic risk factors who still wants systemic therapy, low-to-moderate dose transdermal estradiol is generally the more conservative first choice.

Narrative review, PMC, 2025 (cardiovascular route/dose synthesis). • Shufelt CL, et al. Menopause. 2014;21(3):260–266.

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PATCH TO PATCH

Estradiol Patches: Not All Weekly Schedules Are Equal

Change schedule	Representative brands / generics	Typical dose range	Notes
Once weekly	Climara and generics	0.025–0.1 mg/day	Matrix-type patch; fewer changes to remember
Once weekly (ultra-low dose)	Menostar	0.014 mg/day	Osteoporosis-prevention indication only — not for vasomotor symptoms
Twice weekly (every 3–4 days)	Vivelle-Dot, Minivelle, Dotti, Lyllana	0.025–0.1 mg/day	Reservoir/matrix systems; smaller patch size options available

Know the 2025–2026 supply picture: demand surged after the black-box removal, and several generic patch lines (including twice-weekly Dotti, Lyllana, and select Noven and Zydus products) have run short. Confirm current pharmacy stock before prescribing a specific brand, and have a same-dose alternative (once- vs. twice-weekly, or a different manufacturer) ready to offer.

Dose-equivalence tip: when switching brands or schedules, match the labeled mg/day delivery rate rather than assuming patches of the same nominal strength behave identically — consult a systemic HT equivalency reference.

GoodRx clinical reference, 2025. • MedlinePlus Drug Information, 2025. • Manufacturer package inserts.

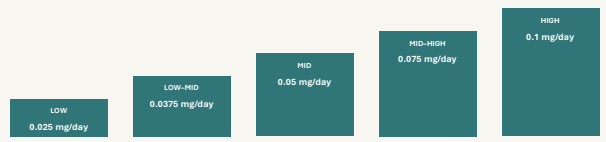
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Estradiol titration ladder

Start to the symptom burden and risk profile—not to a serum estradiol target.

Reassess symptoms, bleeding, adverse effects, adherence, and patient preference; titrate clinically.



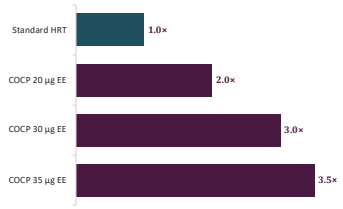
Patch strengths from FDA labeling. Routine serum estradiol monitoring is generally not required for standard menopause therapy.

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ESTROGEN POTENCY

COCP vs HRT: Relative Estrogen Potency

Approximate multiples of a standard HRT dose (10 µg ethinylestradiol ≈ 2 mg oral estradiol valerate)



- Ethinylestradiol (EE) is far more potent than oral estradiol, by as much as 10× per milligram.
- 10 µg EE ≈ 2 mg oral estradiol valerate: the lowest doses that relieve symptoms in most women.
- Even a 20 µg COCP delivers about twice the estrogenic potency of a standard HRT dose.

Takeaway: even low-dose COCPs deliver about 2–3.5× the estrogenic potency of standard HRT.

Thieme Connect, doi:10.1055/s-0038-1646528 • International Menopause Society: The contraceptive needs of the perimenopausal woman. Multiples are derived from dose equivalence.

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PART 4 OF 6

Choosing a Regimen: Progestogen

The partner hormone that protects the endometrium — and may matter for breast safety too.

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THE NON-NEGOTIABLE PARTNER

Any Woman With a Uterus Needs Endometrial Protection

Unopposed systemic estrogen drives endometrial hyperplasia and cancer risk — confirmed since the 1970s and reconfirmed in the randomized PEPI trial. **Progestogen is required** for the full 12–14 days/month (cyclic) or daily (continuous combined) in any woman with an intact uterus.

Agent	Cyclic dose	Continuous dose	Breast / endometrial notes
Micronized progesterone (oral)	200 mg × 12–14 days/mo	100 mg daily	Endometrial protection ≈ MPA; does not increase breast cell proliferation in postmenopausal studies — generally preferred first-line because biochemically similar to endogenous progestin
Medroxyprogesterone acetate (MPA)	5–10 mg × 12–14 days/mo	2.5 mg daily	Endometrial protection well established; synthetic progestin — associated with the added breast cancer signal seen in WHI E+P, WHI used 2.5 mg
Norethindrone acetate (NETA)	Used mainly in combined products	0.35–5 mg daily	Common in fixed-dose combination products; potency differs from MPA — doses are not interchangeable mg-for-mg
LNG-IUD	N/A	52 mg device	Off-label with systemic estrogen in US; useful when contraception/bleeding also matter

Micronized progesterone is peanut-oil based (soy/peanut allergy consideration) and taken at bedtime — it has a mild sedative metabolite that helps with sleep.

BMS Tools for Clinicians: Progestogens and Endometrial Protection, 2026 (Stute P, et al. 2016). • Stute P. Climacteric. 2012;15(5):429–438.

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SEQUENCING THE REGIMEN

Cyclic vs. Continuous Combined

Cyclic (sequential)

- Progestogen given 12–14 days each month
- Produces a predictable monthly withdrawal bleed
- Typically favored in perimenopause / early postmenopause, when unscheduled bleeding on continuous regimens is more common
- Higher progestogen dose per exposed day than continuous regimens

Continuous combined

- Estrogen and progestogen taken together daily, no break
- Goal is amenorrhea after an initial adjustment period of irregular spotting
- Generally reserved for women ≥1 year past their final menstrual period
- Lower daily progestogen dose is often sufficient given constant exposure

Shared-decision point: bleeding tolerance, time since final menstrual period, and patient preference — not a fixed protocol — should drive the choice.

Hamoda H, et al. Post Reprod Health. 2022;28(1) (BMS Tools for Clinicians).

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Combination products: convenience vs flexibility

Bijuva: *oral daily* estradiol + micronized progesterone (0.5/100 or 1/100 mg).

CombiPatch: *transdermal weekly* estradiol 0.05 mg/day + norethindrone acetate 0.14 or 0.25 mg/day.

Climara Pro: *transdermal weekly* estradiol 0.045 mg/day + levonorgestrel 0.015 mg/day.

Fixed combinations simplify adherence—but limit independent titration of estrogen and progestogen.

FDA prescribing information: Bijuva; CombiPatch; Climara Pro.

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Bleeding on MHT: set expectations

- ***Cyclic regimens*** are designed to bleed
- ***Continuous regimens*** may spot initially

- *New, persistent, heavy, or recurrent postmenopausal bleeding still requires evaluation*
- *Check adherence and whether progestogen exposure is adequate for the estrogen dose*
- *Do not reflexively stop useful estrogen forever—evaluate the endometrium and fix the regimen*

Standard postmenopausal bleeding evaluation principles apply; unexplained bleeding is a contraindication to starting systemic MHT.

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PART 5 OF 6

Getting It Covered: Billing & Coding

The visit and the prescription both need to survive prior authorization.

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DIAGNOSIS CODING

ICD-10-CM: Three Codes Cover Most Visits

Code	Description	When to use
N95.1	Menopausal and female climacteric states	Symptomatic menopause — hot flashes, night sweats, GU symptoms; primary diagnosis for most HT visits
Z78.0	Asymptomatic menopausal state	Menopause without current symptoms — do not pair with N95.1 for the same visit
Z79.890	Long-term (current) hormone replacement therapy	Secondary code signaling ongoing HT use — always pair with a primary diagnosis (never stands alone)

Documentation that prevents denials

- Document specific symptoms, their frequency, and severity — not just "menopausal"
- Link Z79.890 explicitly to the qualifying primary diagnosis in your assessment
- For osteoporosis-prevention rationale, document bone density risk factors or DEXA results

ICD-10-CM 2026 code set (icd10data.com). • Mothershed J, CPC. Medical Coding and Billing for Menopause in 2026. 26

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PROCEDURE CODING & COVERAGE

Making the Visit — and the Prescription — Pay

Visit-level CPT coding

Use case	CPT range
Problem-oriented office visit (new/established)	99202–99215
Preventive / wellness visit	99381–99397

If counseling and symptom management drive the visit beyond the preventive-exam scope, a problem-oriented E/M code (with N95.1) captures that additional work — append modifier 25 when billed alongside a preventive visit on the same day.

Prescription coverage tactics

- Generic estradiol patches and oral micronized progesterone are usually preferred-tier — start there before requesting brand-name
- For a prior-authorization denial, document a trial (or contraindication) of a lower tier before requesting a specific branded product
- Low-dose vaginal estrogen often has a simpler coverage pathway than systemic therapy — code and request it separately
- During a patch shortage, ask the pharmacy about manufacturer copay support before switching a stable patient off a working regimen

None of this substitutes for your billing team's payer-specific policy check — requirements vary by plan and change often.

Coding Clarified, Medical Coding and Billing for Menopause in 2026. • ICDcodes.ai, Hormone Replacement Therapy documentation guide, 2026. 27

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North Dakota prescription coverage: know the formulary

ND Medicaid — 2026

Vivelle-Dot remained preferred/no PA in the March 2026 update.

Generic weekly estradiol patch and generic twice-weekly patch required PA.

Dotti, Lyllana, Minivelle were listed non-preferred in that update.

PDL changes during the year—check the current version.

BCBSND — 2026

Formulary includes ***oral estradiol, transdermal gels, and weekly/twice-weekly estradiol patch*** strengths.

Coverage depends on the member's specific formulary and restrictions.

Use electronic PA and document diagnosis, prior trials, intolerance, and route-specific rationale.

ND Medicaid PDL/Provider Newsletter 2026; BCBSND 2026 formulary and pharmacy tools.

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BRINGING IT TOGETHER

Key Clinical Pearls

Timing drives the risk–benefit ratio.
Within 10 years of menopause, or under age 60, is the evidence-supported window for initiating systemic HT.

Estrogen-alone ≠ estrogen + progestin.
They carry different breast cancer profiles — don't extrapolate WHI's combined-arm data to estrogen-only patients.

Route and progestogen choice are levers, not afterthoughts.
Transdermal estrogen and micronized progesterone are reasonable default starting points for many patients.

The label is catching up to the evidence.
As of Nov 2025 – 2026, FDA is removing outdated boxed-warning language product by product — verify current labeling.

Documentation is part of the treatment plan.
Specific symptom detail and correct code pairing (N95.1 / Z78.0 + Z79.890) keep visits and prescriptions covered.

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PART 6 OF 6

Practical Application

What you really need to know to make this work in your practice.

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The benefits that matter clinically

VMS	Most effective therapy for hot flashes/night sweats
Sleep & function	Often improve when VMS are controlled
Bone	Prevents bone loss; reduces fractures while used
GSM	Systemic and local estrogen improve tissue symptoms
Quality of life	Can be transformative in appropriately selected symptomatic patients

ACOG; The Menopause Society; WHI fracture data.

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Who is a good systemic MHT candidate?

- Bothersome ***vasomotor symptoms*** affecting *sleep, function, mood, or quality of life*
- Generally healthy and ***<60 years*** or ***within ~10 years of menopause*** onset

- *NO unexplained vaginal bleeding*
- *NO known estrogen-dependent malignancy requiring avoidance*
- *NO active/prior VTE, stroke, MI, or major thrombophilia* without specialist-level risk assessment

- ***Uterus*** present → adequate ***endometrial protection*** is mandatory

ACOG Hormone Therapy for Menopause; The Menopause Society hormone therapy guidance.

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A 3-minute primary-care MHT risk screen

- Age / years since FMP
- Uterus?
- Unexplained bleeding?
- Breast cancer history / high-risk lesion?
- VTE / thrombophilia?
- Stroke / MI / ASCVD?
- Liver disease?
- Migraine / TG / gallbladder risk?
- Smoking / obesity / BP
- Patient goals & symptom burden

Use clinical history and standard preventive care; routine hormone levels are not required to diagnose menopause in typical women >45.

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Follow-up: what I actually monitor

- ***Symptom response***: VMS, sleep, GSM, function
- ***Bleeding pattern*** and endometrial safety
- ***Adverse effects***: breast tenderness, headache, edema, mood, skin reaction
- ***BP*** and evolving ***cardiovascular/VTE risk factors***
- ***Age-appropriate breast and bone screening***—not extra testing simply because she uses MHT
- ***Annual shared decision***: continue, adjust, change route, taper, or stop based on current goals and risks

No arbitrary mandatory stop date; reassess periodically and individualize.

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CASE EXAMPLE 1 OF 6

Perimenopausal, Needs Contraception

47 years old, irregular periods

SYMPTOMS
- Hot flashes
- Night sweats
- Irritability
- Insomnia

SUGGESTED

Low-dose COCP, taken continuously
- Treats flashes and sweats
- Steadies mood and sleep
- Also provides contraception

ALTERNATIVES
- LNG-IUS plus transdermal estradiol
- CBT for mood and sleep

Illustrative cases only. Individual assessment and local guidelines (NICE NG23, BMS, FSRH) apply. 32

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CASE EXAMPLE 2 OF 6

Postmenopausal, Uterus Intact

53 years old, 14 months since last period

SYMPTOMS
- Hot flashes
- Night sweats
- Vaginal dryness
- Irritability
- Insomnia

SUGGESTED

Continuous combined HRT
- Transdermal estradiol plus micronized progesterone (or LNG-IUS)
- Treats flashes, sweats, mood and sleep
- Add vaginal estrogen if dryness persists

ALTERNATIVES/ADDITIONS
- Tibolone (E2, P4, Testosteone – NOT available in US)
- CBT, SSRI, Trazadone, Veozah/Lynkuet

Illustrative cases only. Individual assessment and local guidelines (NICE NG23, BMS, FSRH) apply. 33

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CASE EXAMPLE 3 OF 6

HRT Not Suitable

56 years old, ER-positive breast cancer on tamoxifen

SYMPTOMS

- Hot flashes
- Night sweats
- Vaginal dryness
- Insomnia

SUGGESTED

Non-hormonal treatment

- Venlafaxine or gabapentin for flashes and sleep
- Vaginal moisturizers and lubricants
- CBT

ALTERNATIVES/ADDITIONS

- Veozah/Lynkuet (monitor liver function)
- Vaginal estrogen only with oncology agreement

Illustrative cases only. Individual assessment and local guidelines (NICE NG23, BMS, FSRH) apply. 34

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Case 4: Typical patient frightened by WHI headlines

52 y/o • LMP 18 months ago • severe VMS • insomnia • normal BP • nonsmoker • NO VTE/ASCVD • uterus present

Treatment: Reasonable starting option: transdermal estradiol 0.025–0.05 mg/day

Add endometrial protection: micronized progesterone regimen if appropriate

Counsel: Discuss expected bleeding pattern, breast screening, VTE warning symptoms, and follow-up

Follow up: Reassess in ~8–12 weeks; titrate to symptom control rather than a serum estradiol number

Example for education—not a patient-specific prescription.

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Case 5: Does route matter?

55 y/o • BMI 36 • VMS • hypertriglyceridemia • migraine without aura • no prior VTE • uterus present

CONSIDER:

- Transdermal estradiol is attractive because it avoids first-pass hepatic effects.
- Use an adequate progestogen strategy.
- Address BP, smoking status, lipids, weight, and baseline vascular risk—MHT is not a substitute for risk-factor management.
- Systemic therapy may still be reasonable after individualized assessment.

ACOG route-of-administration guidance supports considering transdermal estrogen for thrombosis-sparing properties.

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Case 6: 72-year-old asking to start

72 y/o • 20 years post-menopause • new sleep complaints • occasional warmth • NO prior MHT

CONSIDER:

- Do not assume symptoms are menopausal—evaluate other causes
- De novo systemic MHT initiation this far from menopause generally has a less favorable benefit–risk profile
- If the complaint is isolated GSM, use local therapy rather than systemic estrogen
- Continuation at 72 in a woman who started at 52 is a different clinical question

The Menopause Society / ACOG: risk rises with older age and greater time since menopause.

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Five myths to retire in 2026

"All HRT causes breast cancer."	No—risk differs by estrogen-alone vs combined therapy, regimen, duration, and patient.
"WHI proved hormones are dangerous for everyone."	No—WHI was a prevention trial with specific oral regimens and a mean age ~63.
"Never use hormones after 5 years."	No fixed universal stop date; reassess risks and goals.
"Vaginal estrogen carries the same risk as systemic estrogen."	Low-dose local therapy has very different systemic exposure.
"Bioidentical means compounded."	FDA-approved estradiol and micronized progesterone are bioidentical molecules.

Evidence synthesis: ACOG; The Menopause Society; WHI follow-up; FDA.

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TAKE-HOME

HRT in 2026 is not a reversal of science.

It is better interpretation of the science.

Treat the symptomatic patient—not the 2002 headline.

Age, timing, route, formulation, and uterus status matter.

Transdermal estradiol + appropriate progestogen is a highly practical modern strategy.

Do not use MHT as a blanket chronic-disease-prevention drug.

Shared decision-making is the endpoint—not fear and not hype.

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Full list of trial-registry, FDA, and package-insert sources available on request.

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Thank You

Questions & Discussion

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