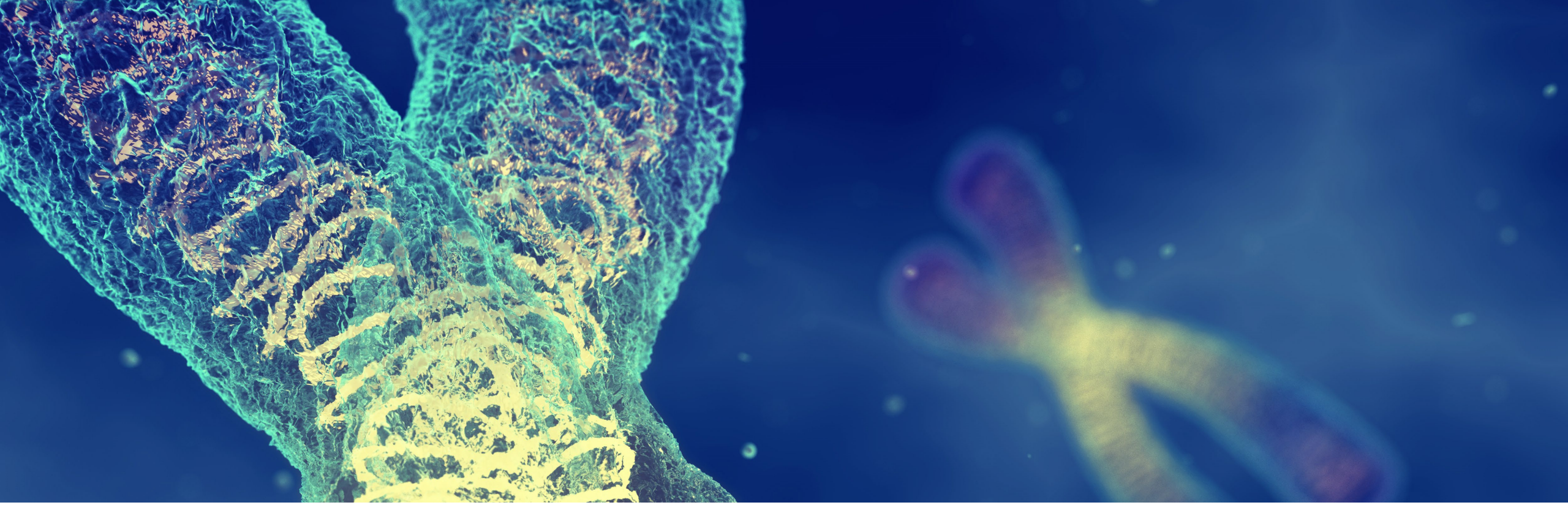

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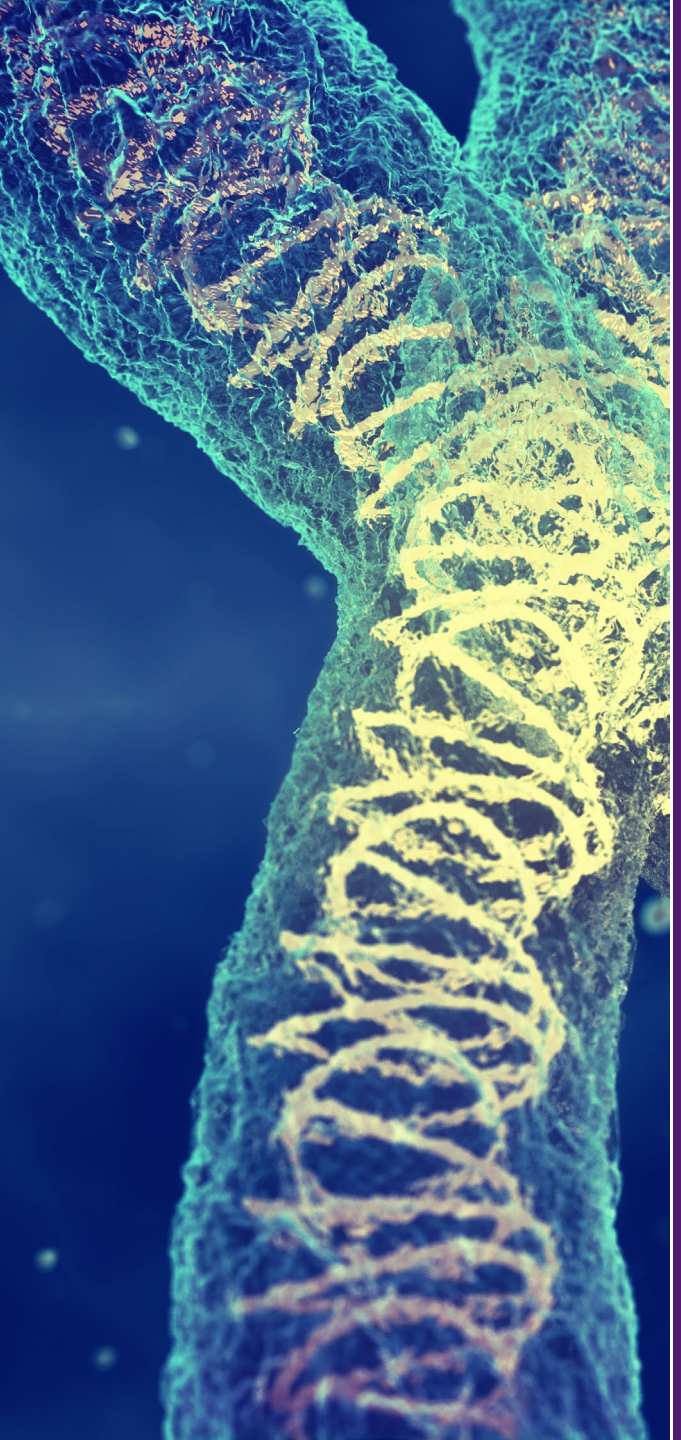
The views expressed in this educational program are those of the faculty and do not necessarily represent the views of the Endocrine Society.



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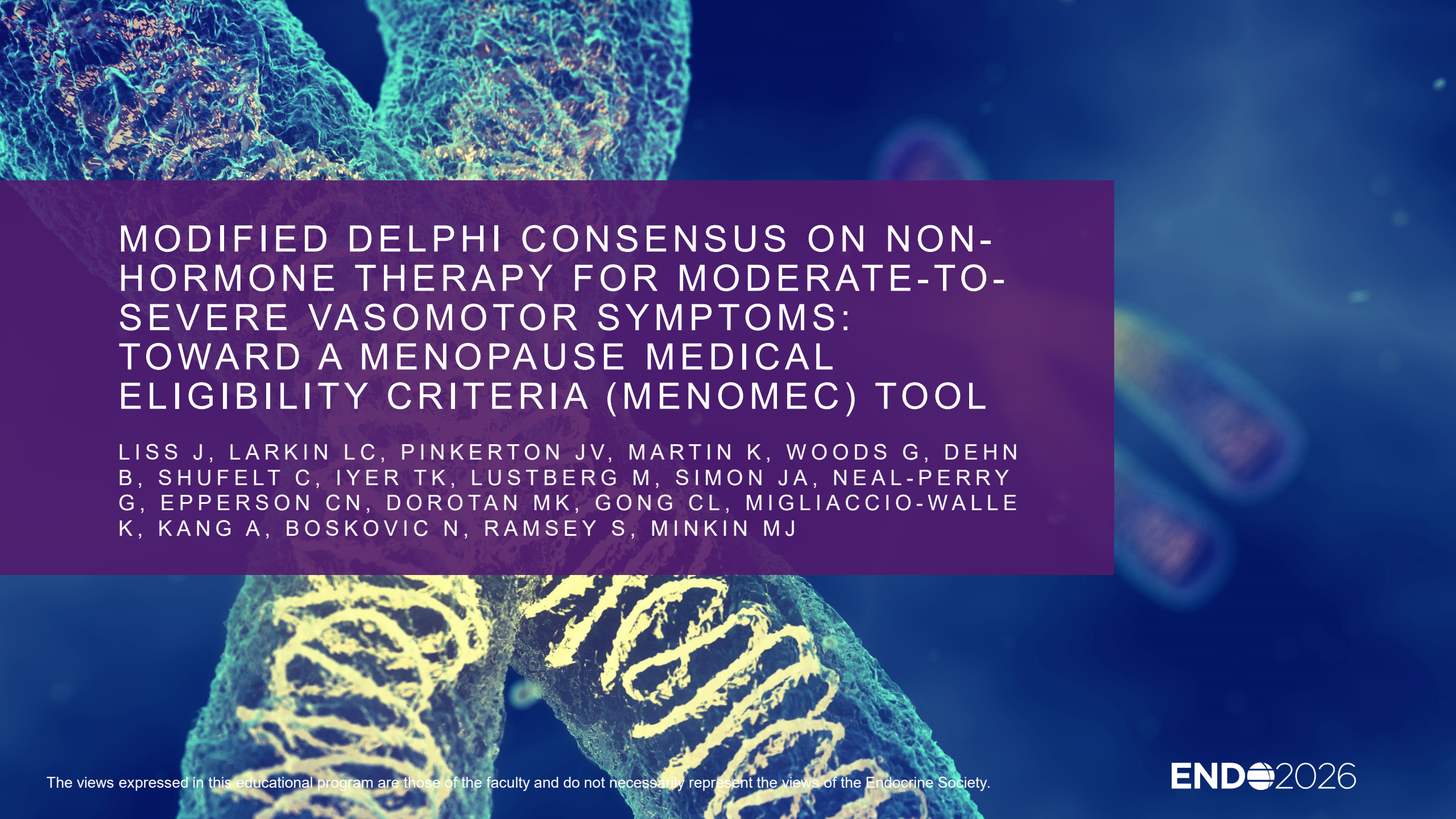

MODIFIED DELPHI CONSENSUS ON NON-HORMONE THERAPY FOR MODERATE-TO-SEVERE VASOMOTOR SYMPTOMS: TOWARD A MENOPAUSE MEDICAL ELIGIBILITY CRITERIA (MENOMEC) TOOL

LISS J, LARKIN LC, PINKERTON JV, MARTIN K, WOODS G, DEHN B, SHUFELT C, IYER TK, LUSTBERG M, SIMON JA, NEAL-PERRY G, EPPERSON CN, DOROTAN MK, GONG CL, MIGLIACCIO-WALLE K, KANG A, BOSKOVIC N, RAMSEY S, MINKIN MJ

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DISCLOSURES

All authors received financial support from Bayer to conduct this study. The views expressed in this educational program are those of the faculty and do not necessarily represent the views of the Endocrine Society nor those of Bayer.

BACKGROUND & RATIONALE

- Menopausal vasomotor symptoms (VMS; also known as hot flashes or night sweats) are common and disruptive
- Hormone therapy (HT) is first-line, but contraindicated or declined in many women
- Non-hormone therapy (NHT) options exist, but US comorbidity-specific guidance is lacking
- We present structured, consensus-based guidance for NHT use in VMS

KEY: HT – hormone therapy; NHT – non-hormone therapy; US – United States; VMS – vasomotor symptoms of menopause

OBJECTIVES

- ESTABLISH CONSENSUS RECOMMENDATIONS ON THE USE OF NHT FOR MODERATE-TO-SEVERE VMS
- DEVELOP COMORBIDITY-SPECIFIC HT VS. NHT GUIDANCE
- CREATE A MENOMEC TOOL FOR WOMEN'S HEALTHCARE PROVIDERS

KEY: HT – hormone therapy; MEC – medical eligibility criteria; NHT – non-hormone therapy; VMS – vasomotor symptoms of menopause

STUDY DESIGN

Methods

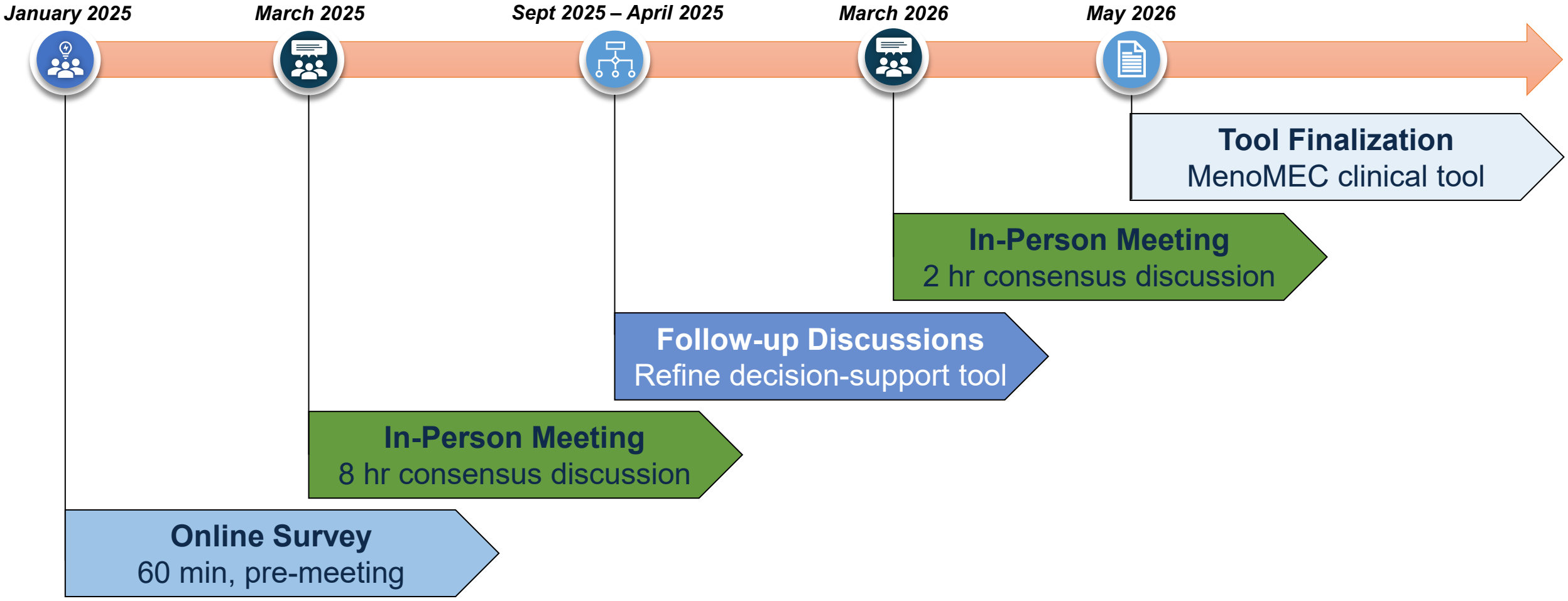
- Modified Delphi panel with 15 multidisciplinary experts
- Systematic review of US guidelines (2014–2024)
- Online survey with 9-point Likert scale to assess agreement
- ≥70% agreement = consensus

Consensus Process

- In-person meeting (Boston, March 2025) for non-consensus items
- Three follow-up discussions to refine recommendations
- One additional in-person meeting to refine recommendations

Specialties included: OB/GYN, cardiology, endocrinology, hematology, neurology, psychiatry, oncology, nursing, as well as primary care, internal medicine, and family medicine

STUDY TIMELINE



RESULTS

- HT remains first-line where eligible
- NHT (SSRI/SNRI, gabapentin, oxybutynin) when HT contraindicated
- NK-receptor antagonists (fezolinetant, elinzanetant): high evidence, access limited but improving
- **Do not recommend** clonidine and most herbal/OTC products

Primary Menopausal Symptom	Recommended First-Line Treatment	Alternative or Second-Line Treatment
VMS; also known as hot flashes or night sweats	NK-receptor antagonists	SSRI/SNRI (e.g., venlafaxine, paroxetine 7.5mg daily), Gabapentin, Oxybutynin
Sleep disturbances	Gabapentin (nighttime dosing)	CBT, SSRI/SNRI
Depression/Anxiety	SSRI/SNRI	CBT, lifestyle modifications
Urinary symptoms / GSM	Local vaginal therapy	Oxybutynin
Pain (MSK, joint, chronic)	Gabapentin or Duloxetine	CBT, lifestyle interventions
Cognitive concerns	SSRI/SNRI or NK-receptor antagonists	Lifestyle modifications
Weight Gain / Metabolic Risk	Lifestyle modifications (exercise, weight loss, CBT)	
Sexual Dysfunction	Vaginal estrogen + NHT	

KEY: CBT – cognitive behavioral therapy; GSM – genitourinary symptoms of menopause; HT – hormone therapy; MSK – musculoskeletal pain; NHT – non-hormone therapy; NK – neurokinin; OTC – over-the-counter; SNRI – selective norepinephrine reuptake inhibitor; SSRI – selective serotonin reuptake inhibitor

COMORBIDITY-SPECIFIC GUIDANCE

- **Therapies rated:** HT (transdermal/oral), approved NHT (NK-receptor antagonist, paroxetine), off-label NHT (gabapentin, oxybutynin, SSRIs/SNRIs)
- **13 comorbid conditions:** age, smoking, ASCVD/PREVENT score, CVD, metabolic, breast cancer (risk + history), gynecologic and other cancer, GI, neuro, thrombosis, autoimmune
- **Initiation vs. continuation** guidance, with footnotes for clinical considerations

Rating

1 No restrictions
2 Benefits > risks
3 Risks > benefits
4 Unacceptable

KEY: ASCVD – atherosclerotic cardiovascular disease; CVD – cardiovascular disease; GI – gastrointestinal; HT – hormone therapy; NHT – non-hormone therapy; NK – neurokinin; PREVENT – Predicting Risk of Cardiovascular Disease EVENTs; SNRI – selective norepinephrine reuptake inhibitor; SSRI – selective serotonin reuptake inhibitor

Medical Eligibility Criteria Guidance Summary: Therapies for Vasomotor Symptoms of Menopause (USA)

The recommendations in this document are based on the best available evidence and expert opinion; all treatment decisions warrant a discussion with the treating clinician and any relevant specialties when initiating or continuing therapy for the treatment of vasomotor symptoms. In addition to the comorbid conditions listed here, all potential drug-drug interactions should be evaluated to determine appropriate initiation or continuation of therapy. Pregnancy should be excluded if patient is perimenopausal.

Condition	Sub-Condition	Hormone Therapy[a,b]				Non-Hormone Therapy												Notes
		On-Label				On-Label						Off-Label						Please refer to footnotes a,b
		Transdermal		Oral Neurokinin		Receptor Antagonist Therapies (NKT: elinzanetant, fezolinetant)				Paroxetine (Brisdelle®)		Gabapentin		Oxybutynin[c]		Other SSRIs / SNRIs[d]		[c]This is applicable to women >65 years. Cognitive decline was reported with oxybutynin use among patients with and without baseline cognitive impairment. Oxybutynin use was linked to functional, mental, and behavioral decline among patients with Alzheimer's disease. [d]SSRIs/SNRIs may include fluoxetine, citalopram, escitalopram, sertraline, duloxetine, venlafaxine, desvenlafaxine. Note: Paroxetine and fluoxetine are potent CYP2D6 inhibitors and may reduce tamoxifen conversion to endoxifen in patients on adjuvant endocrine therapy.
						Elinzanetant		Fezolinetant										
	I=Initiation of Therapy; C=Continuation of Therapy	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	
Age	<45 years[e]	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	[e]COCs are generally more effective for perimenopausal symptom control and provide contraception; however, HT may be used when COCs are not appropriate or not preferred. [f]Older women (aged >70 years) should be assessed annually for risks vs benefits of continuing HT. If ASCVD score >10%, HT should be discontinued.
	45–59 years	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
	60–69 years	2-3	2	3	2-3	1	1	1	1	1	1	1	1	2	2	1	1	
	≥70 years[f]	3	2-3	3-4	3	1-2	1-2	1-2	1-2	2	2	2-3	2-3	3	3	2	2	
Smoking	Current	2	2	3	3	1	1	1	1	2	2	1	1	1	1	1	1	
	Past history	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
ASCVD / PREVENT* 10 yr Risk Score[g]	Low risk: ≤5% / 5%*	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	[g]If hypertension is controlled, HT, regardless of mode of administration, is reasonable. Avoid HT in individuals with uncontrolled hypertension. High-risk threshold varies by calculator: ≥20% (ASCVD) or ≥10% (PREVENT) = Category 4. Apply threshold consistent with calculator used.
	Borderline risk: 5%–7.5% / not explicitly defined*	2-3	2-3	2-3	2-3	1	1	1	1	1	1	1	1	1	1	1	1	
	Intermediate risk: 7.5%–19.9% / 5%–10%*	3	3	3	3	1	1	1	1	1	1	1	1	1	1	1	1	
	High risk: ≥20% / ≥10%*	4	4	4	4	1	1	1	1	1	1	1	1	1	1	1	1	
Known Cardiovascular Disease	Stroke / TIA	3-4	3-4	4	4	1	1	1	1	1	1	1	1	1	1	1	1	
	Nonfatal AMI	3	3	4	4	1	1	1	1	1	1	1	1	1	1	1	1	
	Angina	3	3	4	4	1	1	1	1	1	1	1	1	1	1	1	1	

KEY: 1 = No restriction for use 2 = Advantages generally outweigh theoretical or proven risks 3 = Theoretical or proven risks usually outweigh the advantages 4 = Unacceptable health risk (not to be used)

[a]All individuals should be assessed for cardiovascular risk, ASCVD (or PREVENT) risk score, and breast cancer risk prior to starting HT. [b]Progestogen therapy is required in all individuals with a uterus. Conjugated estrogens/bazedoxifene (Duavee®) may be used in women who are not candidates for progestogens.

Medical Eligibility Criteria Guidance Summary: Therapies for Vasomotor Symptoms of Menopause (USA)

The recommendations in this document are based on the best available evidence and expert opinion; all treatment decisions warrant a discussion with the treating clinician and any relevant specialties when initiating or continuing therapy for the treatment of vasomotor symptoms. In addition to the comorbid conditions listed here, all potential drug-drug interactions should be evaluated to determine appropriate initiation or continuation of therapy. Pregnancy should be excluded if patient is perimenopausal.

Condition	Sub-Condition	Hormone Therapy[a,b]				Non-Hormone Therapy												Notes
		On-Label				On-Label						Off-Label						Please refer to footnotes a,b
		Transdermal		Oral		Neurokinin Receptor Antagonist Therapies (NKT: elinzanetant, fezolinetant)				Paroxetine (Brisdelle®)		Gabapentin		Oxybutynin[c]		Other SSRIs / SNRIs[d]		[c]This is applicable to women >65 years. Cognitive decline was reported with oxybutynin use among patients with and without baseline cognitive impairment. Oxybutynin use was linked to functional, mental, and behavioral decline among patients with Alzheimer's disease. [d]SSRIs/SNRIs may include fluoxetine, citalopram, escitalopram, sertraline, duloxetine, venlafaxine, desvenlafaxine. Note: Paroxetine and fluoxetine are potent CYP2D6 inhibitors and may reduce tamoxifen conversion to endoxifen in patients on adjuvant endocrine therapy.
						Elinzanetant		Fezolinetant										
	I=Initiation of Therapy; C=Continuation of Therapy	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	
Metabolic[h]	BMI >25 kg/m^2	1	1	1-2	1-2	1	1	1	1	1	1	1	1	1	1	1	1	[h]GLP-1 use and/or bariatric surgery should be assessed; may consider non-oral progestin for endometrial protection. [i]If A1C <7%, okay to initiate/continue HT. The goal should always be to control A1C prior to prescribing HT for risk reduction, but also due to the potential for symptom overlap. For isolated uncontrolled diabetes, risks generally outweigh the benefits for both non-oral and oral HT formulations.
	Diabetes – controlled[i]	1	1	2	2	1	1	1	1	1	1	1	1	1	1	1	1	
	Diabetes – uncontrolled	2	2	3	3	1	1	1	1	1	1	1	1	1	1	1	1	
	Hypercholesterolemia	1	1	3	3	1	1	1	1	1	1	1	1	1	1	1	1	
	Hypertriglyceridemia	2	2	3	3	1	1	1	1	1	1	1	1	1	1	1	1	
Risk of Breast Cancer[j,k,m]	Genetic mutation carrier no uterus (E alone)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	[l]Risk/benefit influenced by individual status post hysterectomy (can use estrogen [E] alone) vs not (must use E+P). [k]Risk/benefit influenced by individual tumor histology. [l]Risk/benefit influenced by formulation used CEE vs estradiol; synthetic progestin vs progesterone; CEE+BZA. [m]All discussions about MHT in breast cancer survivors should involve the patient's oncologist.
	Genetic mutation carrier with uterus (E+P)	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	
	Genetic mutation carrier status post bilateral mastectomy	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
	Histologic high risk (ADH, ALH, LCIS)	3	3	3	3	1	1	1	1	1	1	1	1	1	1	1	1	
	Prior chest radiation for other non-breast cancer, eg, Hodgkin	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	
	Model-based high risk (TCV8 >5% 5-year risk or >20% lifetime risk or GAIL >3%)	2-3	2-3	2-3	2-3	1	1	1	1	1	1	1	1	1	1	1	1	
History of Breast Cancer[j-m]	TNBC (>5 yrs / ≤5 yrs)	2/3	2/3	2/3	2/3	1	1	1	1	1	1	1	1	1	1	1	1	
	HR positive – on endocrine therapy	4	4	4	4	1	1	1	1	1	1	1	1	1	1	1	1	
	HR positive – completed endocrine therapy	3	3	3	3	1	1	1	1	1	1	1	1	1	1	1	1	
	DCIS with breast conservation – on endocrine therapy	4	4	4	4	1	1	1	1	1	1	1	1	1	1	1	1	
	DCIS with breast conservation – completed endocrine therapy	3	3	3	3	1	1	1	1	1	1	1	1	1	1	1	1	
	DCIS status post bilateral mastectomy[k]	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	
	Invasive HR negative (<5 years)	3	3	3	3	1	1	1	1	1	1	1	1	1	1	1	1	
	Invasive HR negative (>5 years)	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	
	Invasive HR positive – on endocrine therapy	4	4	4	4	1	1	1	1	1	1	1	1	1	1	1	1	
	Invasive HR positive – completed endocrine therapy	3	3	3	3	1	1	1	1	1	1	1	1	1	1	1	1	

KEY: 1 = No restriction for use 2 = Advantages generally outweigh theoretical or proven risks 3 = Theoretical or proven risks usually outweigh the advantages 4 = Unacceptable health risk (not to be used)

[a]All individuals should be assessed for cardiovascular risk, ASCVD (or PREVENT) risk score, and breast cancer risk prior to starting HT. [b]Progestogen therapy is required in all individuals with a uterus. Conjugated estrogens/bazedoxifene (Duavee®) may be used in women who are not candidates for progestogens.

Condition	Sub-Condition	Hormone Therapy[a,b]				Non-Hormone Therapy												Notes
		On-Label				On-Label						Off-Label						Please refer to footnotes a,b
		Transdermal		Oral		Neurokinin Receptor Antagonist Therapies (NKT: elinzanetant, fezolinetant)				Paroxetine (Brisdelle®)		Gabapentin		Oxybutynin[c]		Other SSRIs / SNRIs[d]		[c]This is applicable to women >65 years. Cognitive decline was reported with oxybutynin use among patients with and without baseline cognitive impairment. Oxybutynin use was linked to functional, mental, and behavioral decline among patients with Alzheimer's disease. [d]SSRIs/SNRIs may include fluoxetine, citalopram, escitalopram, sertraline, duloxetine, venlafaxine, desvenlafaxine. Note: paroxetine and fluoxetine are potent CYP2D6 inhibitors and may reduce tamoxifen conversion to endoxifen in patients on adjunct ET.
						Elinzanetant		Fezolinetant										
	I=Initiation of Therapy; C=Continuation of Therapy	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	
History of Gynecological Cancer	Cervical[n]	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	[n]Category 1 applies to squamous cell histology. Cervical adenocarcinoma (~10% of cases) may warrant management consistent with endometrial cancer guidance; consider histology when counseling. [o]Systemic HT is not recommended in women with advanced uterine (stage III/IV and/or high grade) cancer and uterine sarcomas. [p]Stage of cancer and active metastatic disease play a role in determining the appropriateness of HT. Further discussion with the treating oncologist is warranted to determine optimal therapy selection. No HT should be administered in metastatic disease.
	Uterine[o]	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	
	Ovarian[p]	2-3	2-3	2-3	2-3	1	1	1	1	1	1	1	1	1	1	1	1	
	Epithelial (post-treatment)	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	
	High-grade serous or endometrioid	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	
	Low-grade serous (FIGO Stage I)	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	
	Low-grade serous (FIGO Stage II–IV or recurrent)	4	4	4	4	1	1	1	1	1	1	1	1	1	1	1	1	
	Borderline ovarian tumor	1-2	1-2	1-2	1-2	1	1	1	1	1	1	1	1	1	1	1	1	
	Germ cell tumor (post-treatment)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
	Granulosa cell tumor (Stage I)	3	3	3	3	1	1	1	1	1	1	1	1	1	1	1	1	
History of Other Cancer[q]	Colon	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	[q]Patients with cancer often experience hypercoagulable state. In cases of hypercoagulability, transdermal HT is preferred vs oral therapy.
	Lung	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
	Melanoma	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	
Gastroenterological[r]	LFTs >2x ULN	2	1-2	2-3	2	4	3-4[s,t]	4	3-4[s,t]	3	3	2	2	1	1	1	1	[r]If there is a new elevation, it does not preclude starting medication but does require appropriate workup and requires continuous monitoring. [s]If LFTs increase >5x ULN, then discontinue. [t]There may be situations where risk varies and more consideration is required.
	Cirrhosis	2	2	3	3	4	4	4	4	3	3	2	2	1	1	1	1	
	Acute hepatitis	4	3	4	3	3-4[s,t]	3-4[s,t]	3-4[s,t]	3-4[s,t]	3	3	2	2	1	1	1	1	
	History of treated hepatitis C	1	1	3	3	1	1	1	1	3	3	2	2	1	1	1	1	
	Inflammatory bowel disease	1	1	3	3	1	1	1	1	3	3	2	2	1	1	1	1	
	MASLD / elevated LFTs <2x ULN	1	1	2	1	1-2	1-2	2-3[t]	2-3[t]	2	2	1	1	1	1	1	1	

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Abbreviations: ADH, atypical ductal hyperplasia; ALH, atypical lobular hyperplasia; AMI, acute myocardial infarction; ASCVD, atherosclerotic cardiovascular disease; A1C, glycated hemoglobin; BMI, body mass index; BRCA1/2, breast cancer gene 1/2; BZA, bazedoxifene; C, continuation of therapy; CEE, conjugated equine estrogens; COC, combined oral contraceptive; DCIS, ductal carcinoma in situ; DVT, deep vein thrombosis; E, estrogen; E+P, estrogen+progestogen; ET, estrogen therapy; FIGO, International Federation of Gynecology and Obstetrics; GAIL, breast cancer risk assessment tool; GLP-1, glucagon-like peptide-1; HR, hormone receptor; HT, hormone therapy; I, initiation of therapy; LCIS, lobular carcinoma in situ; LFT, liver function test; MASLD, metabolic dysfunction-associated liver disease; MHT, menopause hormone therapy; NHT, nonhormonal therapy; NKT, neurokinin-targeted therapy; PE, pulmonary embolism; PREVENT, Predicting Risk of Cardiovascular Disease EVENTs; SNRI, serotonin and norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor; TCV8, Tyrer-Cuzick version 8; TIA, transient ischemic attack; TNBC, triple-negative breast cancer; ULN, upper limit of normal, VMS, vasomotor symptoms.

[a]All individuals should be assessed for cardiovascular risk, ASCVD (or PREVENT) risk score, and breast cancer risk prior to starting HT. [b]Progestogen therapy is required in all individuals with a uterus. Conjugated estrogens/bazedoxifene (Duavee®) may be used in women who are not candidates for progestogens.

Condition	Sub-Condition	Hormone Therapy[a,b]				Non-Hormone Therapy												Notes
		On-Label				On-Label						Off-Label						Please refer to footnotes a,b
		Transdermal		Oral		Neurokinin Receptor Antagonist Therapies (NKT: elinzanetant, fezolinetant)				Paroxetine (Brisdelle®)		Gabapentin		Oxybutynin[c]		Other SSRIs / SNRIs[d]		[c]This is applicable to women >65 years. Cognitive decline was reported with oxybutynin use among patients with and without baseline cognitive impairment. Oxybutynin use was linked to functional, mental, and behavioral decline among patients with Alzheimer's disease. [d]SSRIs/SNRIs may include fluoxetine, citalopram, escitalopram, sertraline, duloxetine, venlafaxine, desvenlafaxine. Note: paroxetine and fluoxetine are potent CYP2D6 inhibitors and may reduce tamoxifen conversion to endoxifen in patients on adjuvant ET.
						Elinzanetant		Fezolinetant										
	I=Initiation of Therapy; C=Continuation of Therapy	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	
Neurological	Seizures[u]	1	1	1	1	1-2[u]	1-2[u]	1	1	1	1	1	1	1	1	1	1	[u]Please refer to product's prescribing information. [v]Caution with SSRIs due to potential drug interactions with commonly used migraine drugs (eg, triptans). [w]If migraine worsens on HT, discontinue therapy.
	Migraine – no aura[v,w]	1	1	1	1	1	1	1	1	2	2	1	1	1	1	2	2	
	Migraine – aura[v,w]	1	1	1-2	1-2	1	1	1	1	2	2	1	1	1	1	2	2	
Thrombosis (DVT/PE)	Anticoagulation	2	2	3	2-3	1	1	1	1	2	2	1	1	1	1	1	1	
	No anticoagulation	3	3	4	4	1	1	1	1	1	1	1	1	1	1	1	1	
Autoimmune Disease	Antiphospholipid positive	4	4	4	4	1	1	1	1	1	1	1	1	1	1	1	1	
	Systemic lupus erythematosus	2-3	2-3	2-3	2-3	1	1	1	1	1	1	1	1	1	1	1	1	
	Rheumatoid arthritis	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	

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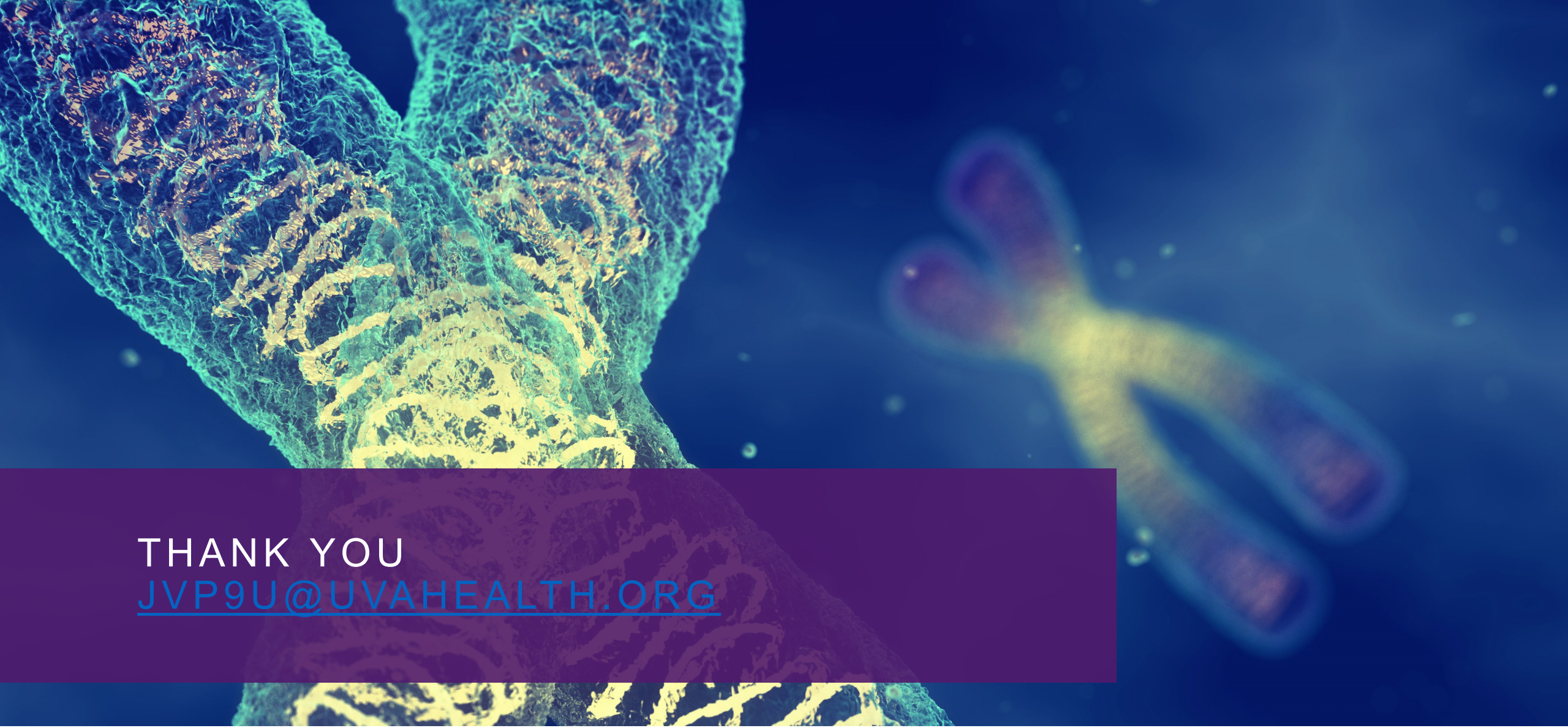
MENOMEC TOOL & CLINICAL IMPLICATIONS

- Decision-support tool for choosing among VMS therapies
- Modeled after WHO MEC for contraception — familiar framework
- Individualizes care by patient comorbidities, with focus on cardiovascular disease, cancer, hepatic disease, and thrombosis
- Will be available as an in-clinic reference card and digital tool
- Publication forthcoming

KEY: MEC – Medical Eligibility Criteria; WHO – World Health Organization; VMS – vasomotor symptoms of menopause



THANK YOU

JVP9U@UVAHEALTH.ORG