Fezolinetant for Vasomotor Symptoms Associated with Menopause: Effectiveness and Value

Public Meeting of the Midwest Comparative Effectiveness Public Advisory Council
December 16, 2022

Meeting materials available at: https://icer.org/assessment/vasomotor-symptoms-menopause-2022/

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MIDWEST CEPAC
AN ICER PROGRAM
COMPARATIVE EFFECTIVENESS PUBLIC ADVISORY COUNCIL

Patient Experts

Claire Gill, Founder, National Menopause Foundation

- *The National Menopause Foundation has received program-specific support totaling less than 25% from Astellas Pharma, Inc. The National Menopause Foundation receives grants and sponsorships from companies including The Pause Group.*

Paula Green-Smith, MA, Chief Training Officer, Black Women's Health Imperative

- *Black Women's Health Imperative receives funding from Hologic Inc., Gilead Sciences, and Myovant-Pfizer.*

Clinical Experts

Stephanie Faubion, MD, MBA
Chair, Department of Medicine
Director, Mayo Clinic Center for Women's Health
Medical Director North American Menopause Society

- *No conflicts of interest to disclose.*

Deborah Grady, MD, MPH
Professor of Medicine, UCSF
Associate Dean for Clinical and Translational Research
Senior Advisor, UCSF Clinical and Translational Science Institute

- *No conflicts of interest to disclose.*

Why are we here today?

The sweating and the abrupt rise in temperature [are the most bothersome] – you know when a hot flash is coming and you are just on fire. And then you know when it's coming to an end because you get cold. So after, you are sitting there and your face is sweaty and gross but you are freezing. It's extremely frustrating.

Woman Experiencing Menopause

Why Are We Here Today?

- What happens the day these treatments receive FDA approval?
- Questions about:
  - Evidence – what are the risks and benefits for individuals?
  - How do new treatments fit into the evolving landscape?
  - What are reasonable prices and costs to patients, the health system, and the government?

The Impact on Rising Health Care Costs for Everyone

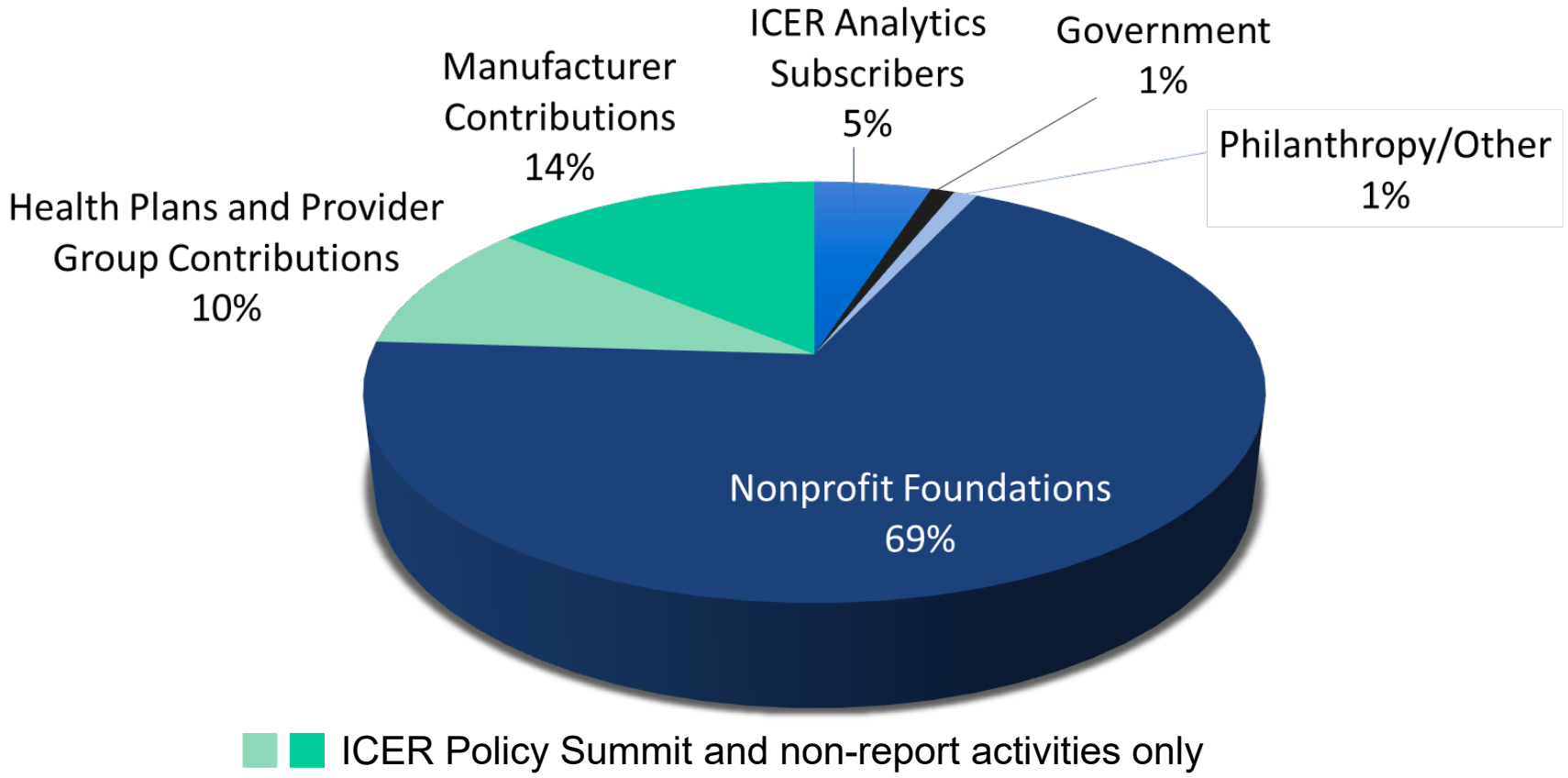
https://khn.org/news/article/diagnosis-debt-investigation-100-million-americans-hidden-medical-debt/

Organizational Overview

- Midwest Comparative Effectiveness Public Advisory Council
- The Institute for Clinical and Economic Review (ICER)

Sources of Funding, 2022

https://icer.org/who-we-are/independent-funding/



How was the ICER report developed?

- Scoping with guidance from patient groups, clinical experts, manufacturer, and other stakeholders
- Internal ICER staff evidence analysis; ICER and University of Colorado cost-effectiveness modeling
- Public comment and revision
- Expert reviewers
  - **Yoko Allen, MPH**, Senior Program Manager, Black Women's Health Imperative
  - **Louise Crathorne, MSc,** Senior Research Fellow in Health Technology Assessment, University of Exeter
  - **Deborah Grady, MD, MPH,** Professor of Medicine, University of California, San Francisco
  - **Kathryn Rexrode, MD, MPH,** Chief, Division of Women's Health, Brigham and Women's Hospital
- How is the evidence report structured to support CEPAC voting and policy discussion?

Value Assessment Framework: Long-Term Value for Money

Value Assessment Framework:
Long-Term Value for Money

Benefits Beyond "Health"

Total Cost Overall
Including Cost Offsets

Health Benefits:
Return of Function, Fewer Side Effects

Health Benefits:
Longer Life

Agenda (CT)

10:00 am	Meeting Convened and Opening Remarks
10:20 am	Presentation of the Clinical Evidence
11:00 am	Presentation of the Economic Model
11:40 am	Public Comments and Discussion
12:00 pm	Lunch Break
12:50 pm	Midwest CEPAC Vote on Clinical Effectiveness and Value
1:50 pm	Break
2:00 pm	Policy Roundtable
3:30 pm	Reflections from Midwest CEPAC
4:00 pm	Meeting Adjourned

Presentation of the Clinical Evidence

Francesca Beaudoin, MD, PhD, MS

Senior Medical Advisor

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Key Collaborators

- Abigail Wright, Senior Research Lead, ICER
- Serina Herron-Smith, Associate Research Manager, ICER
- Shahariar Mohammed Fahim, Research Lead, Evidence Synthesis, ICER

Disclosures:

We have no conflicts of interest relevant to this report

Background: Menopause

- The permanent cessation of menstrual periods = typically determined after 12 months of amenorrhea.
- Depletion of ovarian follicles resulting in a low estrogen state; Median age = 51.4, timing affected by many factors
- Majority of menopausal women** experience vasomotor symptoms (> 80%) with a mean duration 9.4 years.

**ICER recognizes that gender language is evolving and that individuals experiencing menopause may have diverse gender identities. In this report, when we use the word "woman" (and the pronouns "she" and "her") we are describing adult individuals whose biologic sex is female, whether they identify as female, male, or non-binary, among others. When referencing study populations used in specific research studies, we will use the gender language used by the study investigators. As gender language continues to evolve, ICER will periodically reassess this language and make appropriate adjustments as necessary in future versions of this and other reports.

Vasomotor Symptoms (VMS) of Menopause

- Main symptoms are hot flashes and night sweats
  - Likely thermoregulatory dysfunction, lower threshold to eliminate heat
  - Mediated by low estrogen, inappropriate vasodilation/perspiration
- ~40% have moderate to severe VMS that interferes with daily life activities (sleep, mood, concentration, sexual activity)
  - 7 or more episodes/day associated with decreased quality of life
- Variation in duration and severity by race/ethnicity
  - Black Americans have highest burden of VMS symptoms

Standard of Care and Management

- Majority of women don't seek medical care
  - Behavioral changes or OTC meds (e.g., clothing, herbal supplements)
  - Symptoms resolve over time, but gradually
- Menopausal Hormone therapy (MHT)
  - Estrogen ± progesterone in various preparations
  - Many women cannot or will not take MHT due to risk of AEs
- Nonhormonal options are second line
  - SSRI/SNRIs, gabapentinoids have modest and varying effectiveness for VMS

AE: adverse event, FDA: Food and Drug Administration, OTC: over the counter, SNRI: serotonin–norepinephrine reuptake inhibitor, SSRI: selective serotonin reuptake inhibitor

Insights from Discussions with Patients

- VMS (and other symptoms) of menopause have a significant negative impact on day-to-day life: sleep, work, interactions, sexual activity
- Symptoms of menopause are frequently dismissed by health care providers and may go unaddressed
- Strong desire to have options for treatment
- Concern about health inequity and access to treatment options

Fezolinetant

- Neurokinin 3 (NK3) receptor antagonist
  - Nonhormonal therapy
  - Modulates neuronal activity in the hypothalamus
  - Oral, once daily therapy for relief of VMS
  - Application under review by FDA for 45 mg dose
  - First-in-class medication
- Systematic review focused on fezolinetant or MHT versus placebo for women with moderate to severe VMS

Key Outcomes

Severity:

(1) Mild (sensation of heat *without* sweating)

(2) Moderate (sensation of heat *with* sweating and able to continue activity)

(3) Severe (sensation of heat with sweating, causing cessation of activity)

Frequency: (number of moderate to severe episodes, daily or weekly)

Menopause-Specific Quality of Life Questionnaire (MENQoL):

29-item tool covering four domains of menopausal symptoms (vasomotor, psychosocial, physical, and sexual domains)

Clinical Evidence

Fezolinetant: Overview of Evidence, Key Trials

Trial	Dosages	N	Key Outcomes	Follow-Up
Skylight 1 Phase III	30 mg, **45 mg**	522	Change in daily moderate to severe VMS frequency and severity; change in MENQoL	12 weeks
Skylight 2 Phase III	30 mg, **45 mg**	500	Change in daily moderate to severe VMS frequency and severity; change in MENQoL	12 weeks
Skylight 4 Phase III (safety)	30 mg, 45 mg	1830	Number of adverse events	52 weeks
Moonlight 1 Phase III (Asia)	30 mg	302	Change in daily moderate to severe VMS frequency and severity; change in MENQoL	12 weeks
Moonlight 3 Phase III (safety)	30 mg	150	Number of adverse events	52 weeks

Fezolinetant versus Placebo for VMS: Frequency

Difference between 45 mg fezolinetant versus placebo at 12 weeks:

Skylight 1: –2.55, p<0.001 (n=174 in fezolinetant arm)

Skylight 2: –2.53, p<0.001 (n=167 in fezolinetant arm)

Treatment response:
50% reduction in frequency: 58.7% in the fezolinetant versus 36% PBO
75% reduction in frequency: 37% in the fezolinetant versus 17% PBO

MCID: VMS frequency (≥25 per week or 3.57 per day)

PBO: placebo

Fezolinetant versus Placebo for VMS: Severity

Difference between 45 mg fezolinetant versus placebo at 12 weeks:

Skylight 1: –0.20 (95% CI +/- 0.08), p=0.007 (n=174 in fezolinetant arm)

Skylight 2: –0.29 (95% CI +/- 0.08), p<0.001 (n=167 in fezolinetant arm)

*No data was provided on percentage of responders with a 50% or 75% reduction in VMS severity.

*Ordinal categorical variables treated as continuous

MCID: VMS severity ≥0.225 use three-point scale (Mild, Moderate, Severe)

MCID: Minimal clinically important differences

Fezolinetant versus Placebo: Other outcomes

Difference between 45 mg fezolinetant versus placebo at 12 weeks:

MENQoL, Skylight 1 & 2: -0.47 (95% CI: -0.66, -0.28)
*Only pooled data available

MCID: MENQoL (≥1 point in the vasomotor domain, or total score)

Sleep: 51% in 45 mg fezolinetant arm reported “much better” or “moderately better” sleep (PGI-C-SD) compared to 22% in the placebo group.

*Data not available on other outcomes

MHT versus Placebo for VMS: Overview of Key Results

- **Nine studies** examining MHT, heterogenous in dose, routes of administration, and outcomes assessment

- Decrease in **severity** of moderate to severe VMS
  - Range from 0.2 - 1.07 (3 point scale)
  - One trial (low dose estradiol arm) did not exceed MCID
- Decrease in **frequency** of moderate to severe VMS
  - Range from 0.7 - 4.1 episodes per day
  - One trial (transdermal estradiol) did not exceed MCID
- Total **MENQoL** scores not clinically different between MHT versus placebo
- Effective in treating other symptoms of menopause such as vaginal dryness, insomnia

Fezolinetant versus MHT

- No head-to-head trials
- Differences in trial populations and outcome assessments
- VMS **severity** score was similar in only one study and MHT provided approximately 0.6 to 0.8 further reduction in the VMS severity score compared to fezolinetant

Harms

Fezolinetant

- Treatment-related liver enzyme elevation:
  - 2-4% of patients
- Other Most Common AEs:
  - Headache, urinary tract infection, upper respiratory tract infection, cough, fatigue

MHT

- Serious adverse events
  - Venous thromboembolism (OR 1.9-2)
  - Cardiovascular events (OR 0.93-1.26)
  - Breast cancer (OR 1.2-1.3)
- Risks higher in older women (≥60)
- Other Most Common AEs:
  - Uterine bleeding
- Protective against fractures

AE: adverse event, OR: odds ratio

Controversies and Uncertainties

- Generalizability of study populations to the population of women undergoing menopause (e.g., race, ethnicity, natural menopause)
- Heterogeneity of outcomes assessments across trials
- Uncertainty around long-term efficacy and safety of fezolinetant
- Uncertainty around safety of MHT in younger women, lower doses

Contextual Considerations and Potential other Benefits

- Magnitude of lifetime impact: the average duration of VMS is nearly a decade long and can affect sleep, work, and intimate relationships.
- Duration of the trials relatively short compared to the duration of menopause symptoms: the primary outcomes in key fezolinetant trials only assessed efficacy up to 12 weeks.
- Unpredictable flushing and sweating along with insomnia can adversely affect regular activities and work performance.
- There are not caregiver burdens in a traditional sense, but household members or intimate partners may be impacted by certain aspects of VMS such as sleep disruption, mood swings, or concerns related to sexual activity.

Public Comments Received

- Emphasis should be placed on shared-medical decision making and access to both hormonal and nonhormonal options for menopause.
- Underscoring the unmet need for nonhormonal treatment options and the potential impact that these options might have on sub-populations who either experience increased burden of symptoms (e.g., Black women) or in whom MHT is not an option.
- The report should focus on the 45 mg dosing rather than the 30 mg arms of Skylight or the Moonlight trials.

Summary

- Fezolinetant appears promising at the 45 mg dosing, particularly for VMS severity, but longer-term efficacy and safety data are needed.
- Fezolinetant is likely comparable or inferior to MHT, but no head-to-head data exists.
- Fezolinetant may have a role in the real world setting where many women cannot or will not utilize MHT, but current evidence is still inconclusive.

Summary and ICER Evidence Ratings

Treatment	Comparator	Evidence Rating
Fezolinetant	No pharmacologic treatment	P/I
Fezolinetant	Menopausal Hormone Therapy	I

Questions?

Presentation of the Economic Model

Brett McQueen, PhD

Assistant Professor

School of Pharmacy, University of Colorado

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Key Review Team Members

- Ashton Moradi, PharmD, MS, ICER
- Eric Gutierrez, MPH, School of Pharmacy, University of Colorado

Disclosures:

Financial support was provided to the University of Colorado from the Institute for Clinical and Economic Review.

University of Colorado researchers have no conflicts to disclose defined as more than $10,000 in health care company stock or more than $5,000 in honoraria or consultancies relevant to this report during the previous year from health care technology manufacturers or insurers.

Objective

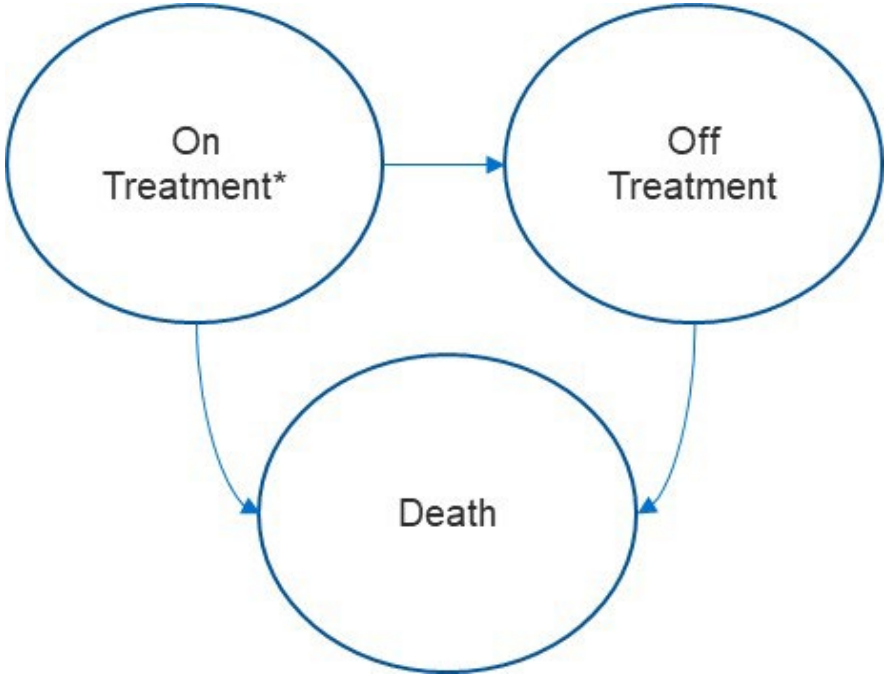
- Assess the lifetime cost-effectiveness of fezolinetant relative to no medical therapy (as estimated by the placebo arms of clinical trials)
  - Emphasis on women who cannot or will not take Menopausal Hormone Therapy (MHT)

Methods in Brief

Methods Overview

- **Population:** Women seeking relief from vasomotor symptoms (VMS) associated with menopause
- **Time horizon:** Lifetime
- **Interventions and comparators:**
  - Fezolinetant (Astellas Pharma, Inc.) versus no pharmacologic treatment (as estimated by the placebo arm of clinical trials)
  - Scenario analysis: Menopausal Hormone Therapy versus no pharmacologic treatment (as estimated by the placebo arm of clinical trials)
- **Outcomes:** Total and incremental costs, quality-adjusted life years (QALY), equal value of life years (evLYs), symptom-free days, and incremental cost-effectiveness ratios

Model Schematic



*In some cases, there may be assignment of on treatment and not responding where treatment and health state costs are incurred with no gain in health benefits.

- Model structure allows for health-related quality of life differences, discontinuation, and cost offsets for treatment versus no treatment

Model Characteristics

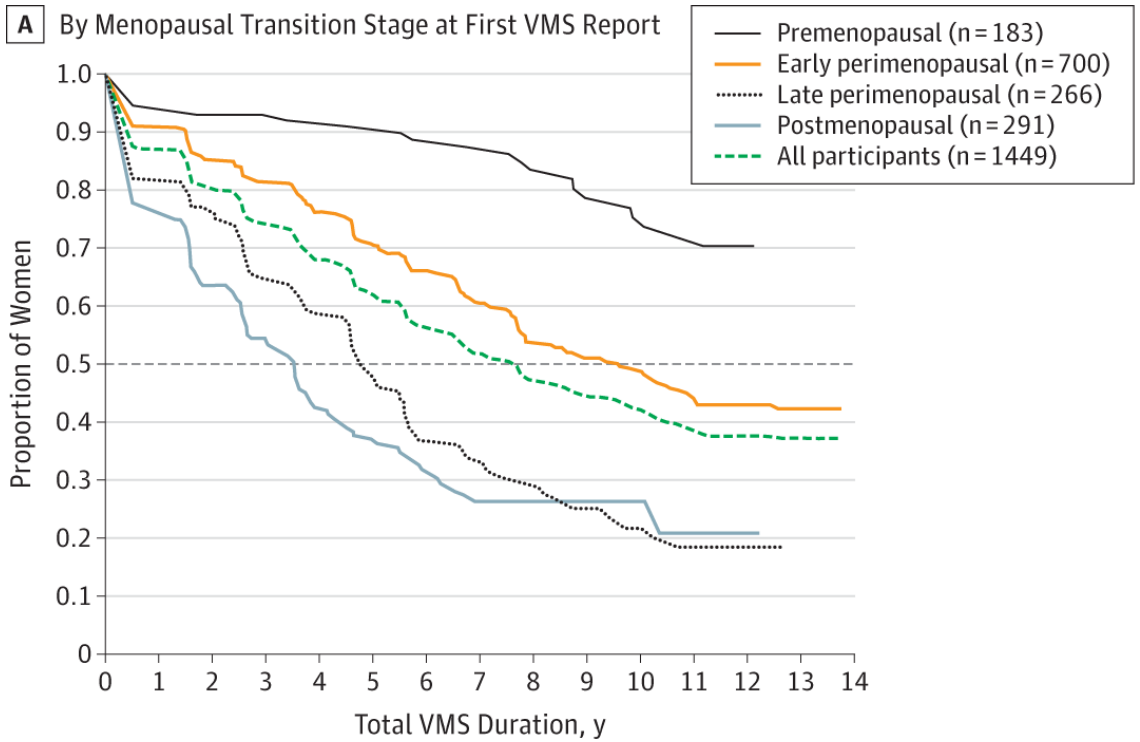
Baseline Characteristic	Value
Mean Age (SD), years	54.3 (5.0)
Duration of VMS, years	Median: 9.4
Baseline daily VMS frequency per 24 hours (range of mean)	9-12
Source	Kimball et al. Skylight 2, ENDO 2022; Fraser et al. Menopause 2020

SD: standard deviation, VMS: vasomotor symptoms

Key Model Assumptions

- Patients not responding to fezolinetant or other active treatments will not be re-treated with the other treatments for VMS.
- Duration of treatment in the model will be consistent with VMS duration and assumed the same for all treatments.
- The effectiveness of fezolinetant and comparators does not wane over time. Fezolinetant and its comparators have no residual benefits after stopping therapy.

Key Model Inputs: Duration of VMS and Treatment



- Transitions between on and off treatment derived from parametric curves fit to Kaplan-Meier plots of symptom duration over the cycle of menopause symptoms

Figure adapted from: Avis, N. E., Crawford, S. L., Greendale, G., Bromberger, J. T., Everson-Rose, S. A., Gold, E. B., ... & Study of Women's Health Across the Nation. (2015). Duration of menopausal vasomotor symptoms over the menopause transition. JAMA internal medicine, 175(4), 531-539.

Key Model Inputs: Costs

Intervention (Dosage)	Price Per Day	Net Annual Cost	Source
Fezolinetant*	$16.43	$6,000	Placeholder price
Menopausal Hormone Therapy	$0.34	$123.45	RedBook

*Placeholder price – interpret future findings with caution. This dosing may be used to estimate incremental cost-effectiveness, but no recommendations will be made around theoretical discounts to achieve cost-effectiveness unless a price is announced by the manufacturer of fezolinetant.

Key Model Inputs: Utilities

Quality of life characteristic	Fezolinetant	Menopausal Hormone Therapy	No Pharmacologic Treatment
Change in total MENQoL score versus placebo (95% CI)	-0.33 (0.00, -0.47)*	-0.42 (-0.23, -0.51)*	Reference group
On treatment health state utility (95% CI)	0.825 (0.81, 0.83)	0.829 (0.82, 0.83)	0.811
Source	Cano et al. IMS Conference Presentation 2022; Astellas Pharma Inc. 2022 Press Release; Coon et al. 2018 Climacteric	Simon et al. 2019 Menopause; Joffe et al. 2014 JAMA Intern Med.; Caan et al. 2020 Menopause	Coon et al. 2018 Climacteric

CI: confidence intervals, MENQoL: Menopause-Specific Quality of Life Questionnaire

*Weighted mean difference from placebo was calculated for each intervention

Results

Base-Case Results

Drug	Intervention Cost	Other Non-Intervention Costs*	Total Costs	QALYs	evLYs	Avg. VMS Episodes Per Day
Fezolinetant	$45,000†	$153,000	$198,000	16.43	16.43	7.54
No Pharmacologic Treatment	$0	$157,000	$157,000	16.33	16.33	10.0

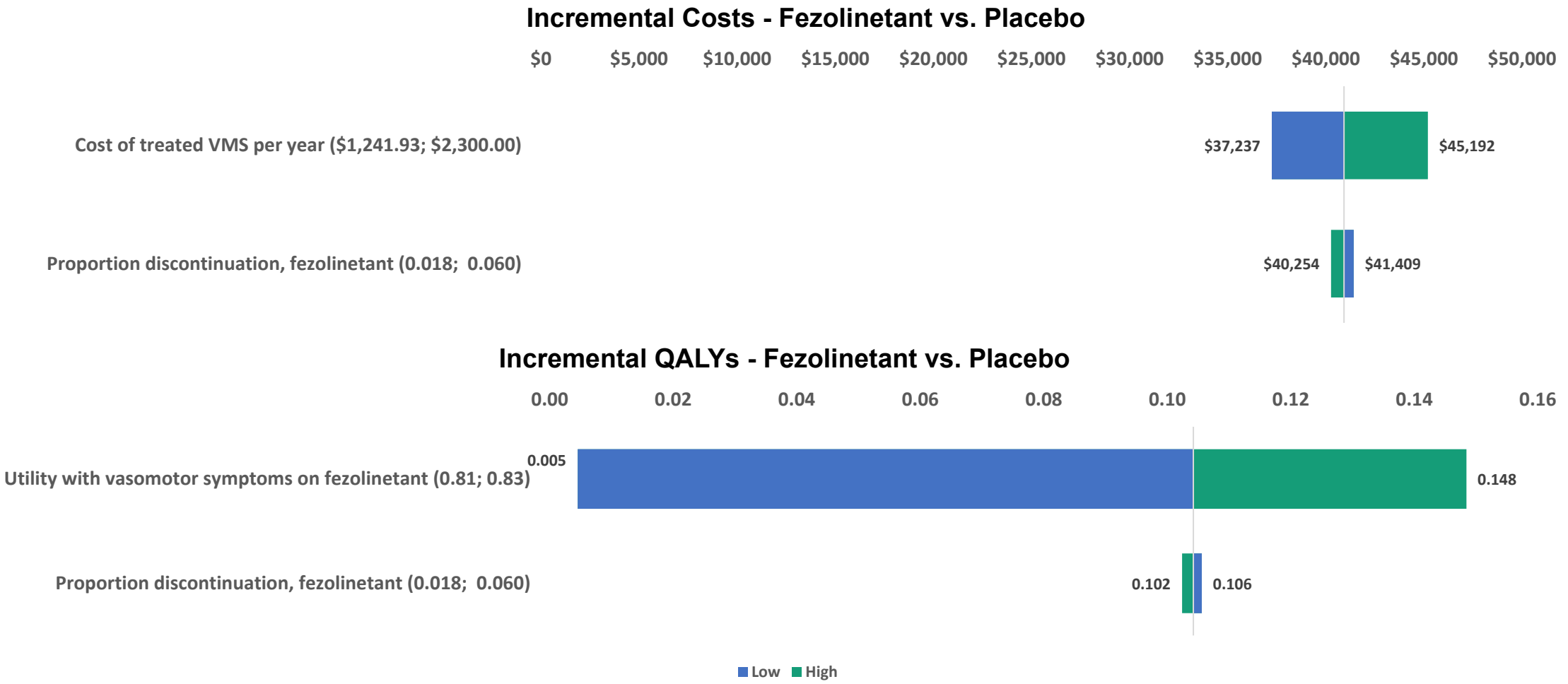
QALYs: quality-adjusted life years, evLYs: equal value of life years, VMS: vasomotor symptoms
*Other non-intervention costs include long-run unrelated health state costs and do not differ between treatment arms in this analysis.
†Based on annual placeholder price of $6,000. Interpret findings with caution.

Base-Case Incremental Results

Drug	Comparator	Cost per QALY Gained	Cost per evLY Gained	Cost per Symptom-free Day
Fezolinetant*	No Pharmacologic Treatment	$390,000	$390,000	$500

QALYs: quality-adjusted life years, evLYs: equal value of life years, VMS: vasomotor symptoms
*Based on annual placeholder price of $6,000. Interpret findings with caution.

One Way Sensitivity Analyses



Probabilistic Sensitivity Analysis

Drug	Cost-Effective at $50,000 per QALY	Cost-Effective at $100,000 per QALY	Cost-Effective at $150,000 per QALY
Fezolinetant*	1%	5%	14%

QALYs: quality-adjusted life years
*Based on annual placeholder price of $6,000. Interpret findings with caution.

Scenario Analyses

Drug	Comparator	Cost per QALY Gained	Cost per evLY Gained	Cost per Symptom-free Day
Menopausal Hormone Therapy	No Pharmacologic Treatment	$13,000	$13,000	$12

evLYs: equal value of life years, QALYs: quality-adjusted life years

Health Benefit Price Benchmarks (HBPBs)

Annual Price Benchmarks for Fezolinetant

Outcome for Annual HBPB Calculation	Annual WAC	Annual Price at $100,000 Threshold	Annual Price at $150,000 Threshold	Discount from WAC to Reach Threshold Prices
Fezolinetant vs. No pharmacologic therapy				
QALYs gained	N/A*	$2,000	$2,500	N/A*
evLYs Gained	N/A*	$2,000	$2,500	N/A*

evLY: equal value life year, HBPB: health benefit price benchmark, QALY: quality-adjusted life year, WAC: wholesale acquisition cost
*Not applicable (N/A) as placeholder prices were used and there is no know price for fezolinetant.

Limitations

- No direct comparisons between fezolinetant and MHT given inconsistency in trial endpoints.
- Relied on mapping instrument for changes in QALYs and evLYs.
- No evidence on treatment effects for cost offsets when using fezolinetant versus placebo.

Comments Received

- Confusion on model structure and health-related quality of life
- Treatment switching and discontinuation inputs
- Utility estimates and alignment with literature sources

Conclusions

- At the placeholder price, the base-case findings suggest fezolinetant provides gains in QALYs and evLYs over no pharmacologic treatment but with increased costs to the health system.
- Key drivers of value include health-related quality of life and cost savings from treatment on fezolinetant.
- Cost-effectiveness of fezolinetant depends upon both its price and the population using it (all women or women who cannot/will not take MHT).

Questions?

Public Comment and Discussion

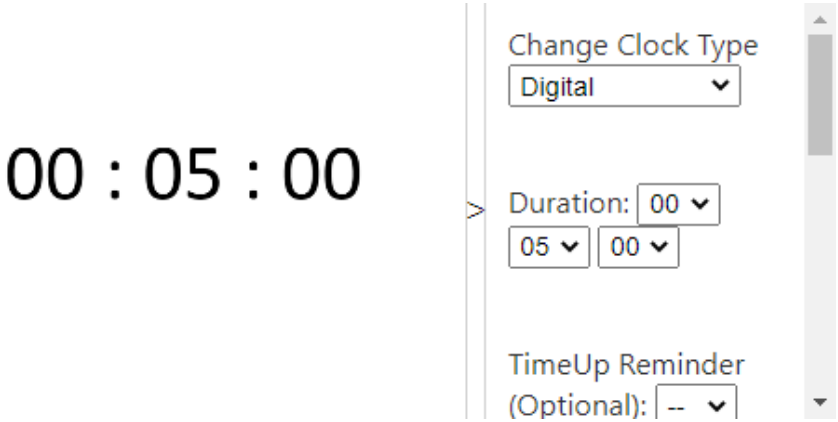
Manufacturer Public Comments

Speaker	Title	Affiliation
Shontelle Dodson, PharmD	Executive Vice President, Head Medical Affairs	Astellas Pharma Inc.

Shontelle Dodson, PharmD
Executive Vice President, Head Medical Affairs, Astellas Pharma Inc.

Conflicts of Interest:

- *Dr. Dodson is a full-time employee of Astellas Pharma Inc.*



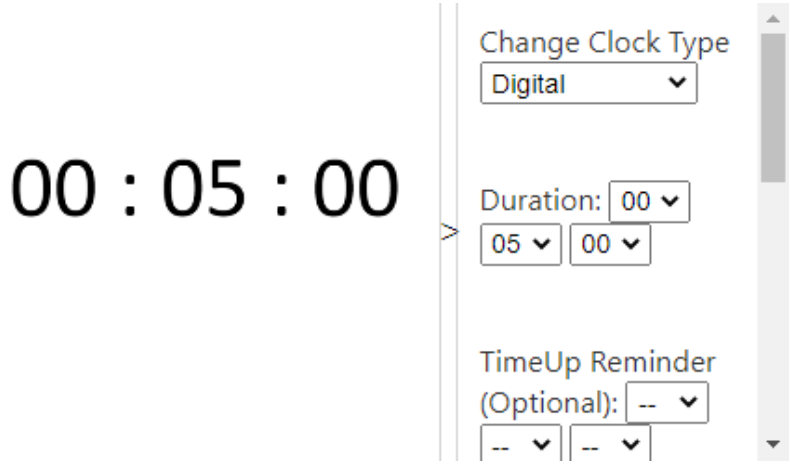
Patient Public Comments

Speaker	Title	Affiliation
Irene Aninye, PhD	Chief Science Officer	Society for Women's Health Research (SWHR)

Irene Aninye, PhD
Chief Science Officer, Society for Women's Health Research

Conflicts of Interest:

- *The Society for Women's Health Research receives more than 25% of its funding from health care companies.*



Lunch

Meeting will resume at 12:50 pm CST

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Voting Questions

Clinical Evidence Questions

Patient population for all questions: Women seeking relief from vasomotor symptoms associated with menopause.

1. Is the currently available evidence adequate to demonstrate that the net health benefit of fezolinetant is superior to that provided by no pharmacologic treatment (neither prescription nor non-prescription) for vasomotor symptoms associate with menopause?

A. Yes

B. No

Patient population for all questions: Women seeking relief from vasomotor symptoms associated with menopause.

2. Is the currently available evidence adequate to distinguish the net health benefit between fezolinetant and menopausal hormone therapy for vasomotor symptoms associated with menopause

A. Yes

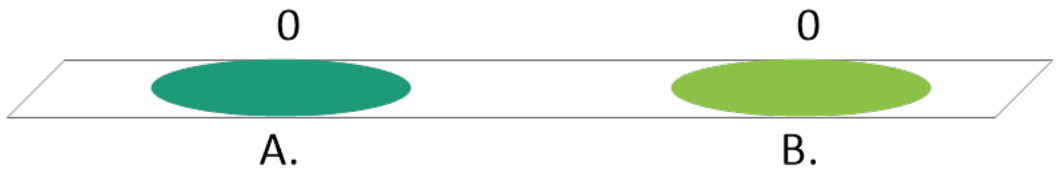
B. No

Patient population for all questions: Women seeking relief from vasomotor symptoms associated with menopause.

2a. Is the currently available evidence adequate to demonstrate that the net health benefit of fezolinetant is superior to that provided by menopausal hormone therapy for vasomotor symptoms associated with menopause?

A. Yes

B. No



Contextual Considerations and Potential Other Benefits or Disadvantages Questions

When making judgements of overall long-term value for money, what is the relative priority that should be given to <u>any</u> effective treatment for vasomotor symptoms associated with menopause, on the basis of the following contextual considerations:

3. Acuity of need for treatment of individual patients based on short-term risk of death or progression to permanent disability.

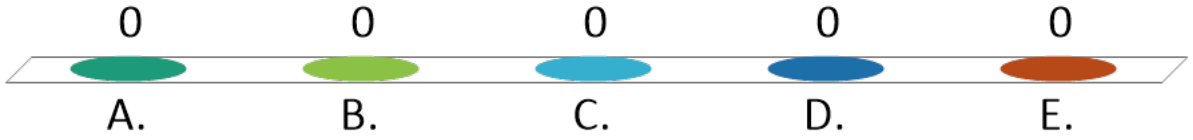
A. Very low priority

B. Low priority

C. Average priority

D. High priority

E. Very high priority



When making judgements of overall long-term value for money, what is the relative priority that should be given to <u>any</u> effective treatment for vasomotor symptoms associated with menopause, on the basis of the following contextual considerations:

4. Magnitude of the lifetime impact on individual patients of the condition being treated.

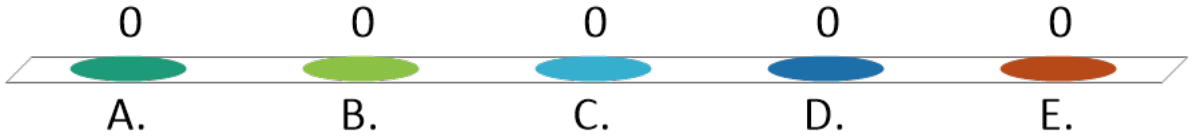
A. Very low priority

B. Low priority

C. Average priority

D. High priority

E. Very high priority



What are the relative effects of fezolinetant versus no pharmacologic treatment (neither prescription nor non-prescription) on the following outcomes that inform judgement of the overall long-term value for money of fezolinetant?

5. Patients' ability to achieve major life goals related to education, work, or family life.

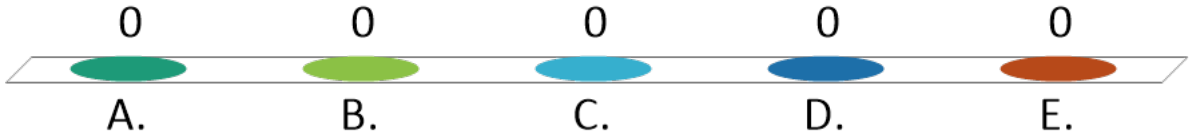
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



What are the relative effects of fezolinetant versus no pharmacologic treatment (neither prescription nor non-prescription) on the following outcomes that inform judgement of the overall long-term value for money of fezolinetant?

6. Caregivers' quality of life and/or ability to achieve major life goals related to education, work, or family life.

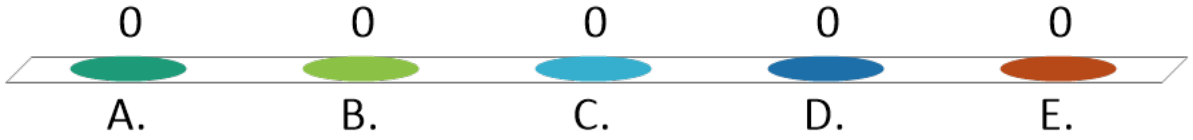
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



What are the relative effects of fezolinetant versus no pharmacologic treatment (neither prescription nor non-prescription) on the following outcomes that inform judgement of the overall long-term value for money of fezolinetant?

7. Society's goal of reducing health inequities

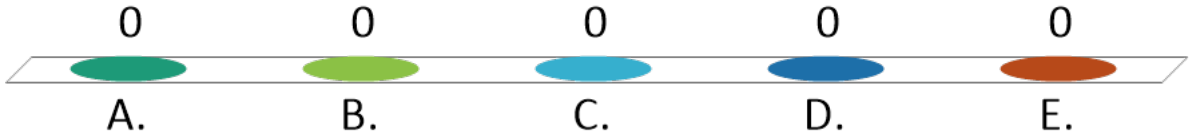
A. Major negative effect

B. Minor negative effect

C. No difference

D. Minor positive effect

E. Major positive effect



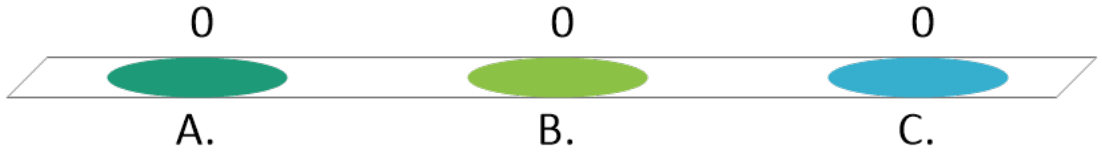
Long-Term Value for Money Questions

8. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at assumed pricing with fezolinetant versus no pharmacologic treatment for vasomotor symptoms?

A. Low long-term value for money at assumed pricing

B. Intermediate long-term value for money at assumed pricing

C. High long-term value for money at assumed pricing



Break

Meeting will resume at 2 pm CST

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Policy Roundtable

Policy Roundtable Participant	Conflict of Interest
Shontelle Dodson, PharmD, Executive Vice President, Head Medical Affairs, Astellas Pharma Inc.	Dr. Dodson is a full-time employee of Astellas Pharma Inc.
Stephanie Faubion, MD, MBA, Director, Center for Women's Health, Mayo Clinic. Medical Director, North American Medical Society	No conflicts to disclose.
Claire Gill, Founder, National Menopause Foundation	The NMF received program-specific support totaling less than 25% from Astellas Pharma, Inc.
Deb Grady, MD, MPH, Professor of Medicine, UCSF	No conflicts to disclose.
Paula Green-Smith, MA, Chief Training Officer, Black Women's Health Imperative	The Black Women's Health Imperative receives funding from Hologic Inc., Gilead Sciences, and Myovant-Pfizer.
Michelle Rogers, PharmD, BCPS, Director, Clinical Pharmacy, IPD Analytics	Dr. Rogers is a full-time employee of IPD Analytics
John Watkins, PharmD, MPH, BCPS, Residency Program Director, Premera Blue Cross, and Affiliate Professor, University of Washington	Dr. Watkins is a half-time employee of Premera Blue Cross.

Midwest CEPAC Council Reflections

Next Steps

- Meeting recording posted to ICER website next week
- Final Report published on or around January 23, 2022
  - Includes description of Midwest CEPAC votes, deliberation, policy roundtable discussion
- Materials available at: https://icer.org/assessment/vasomotor-symptoms-menopause-2022/#timeline

Adjourn

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