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## NAMS Responds to NCQA's HEDIS Measures

March 10, 2020

I would like to share with you the comment we have submitted on behalf of The North American Menopause Society to the National Committee for Quality Assurance (NCQA) regarding consistently classifying estrogen as a high-risk medication for older women despite recommendations to the contrary. This comment urges HEDIS to reconsider this adverse designation of hormone therapy for menopausal women because it is not current, is not accurate, and ultimately harms women by failing to treat them for menopause symptoms, which are exceedingly common and long lasting.

**Below is the comment that NAMS has submitted. We would also encourage all NAMS members to consider submitting a personal comment directly to NCQA on this important issue and have included details below on how to do that.**

### NAMS Submission

The North American Menopause Society (NAMS) wishes to comment on the NCQA's HEDIS Measures to address the recommendations against the use of oral and transdermal estrogens with or without progestins as described in the 2018 Beers List for medications that are "potentially inappropriate for older adults, with updates in 2019." Inclusion of these medications on a list that results in denial of services for women aged older than age 65 years is discriminatory and deprives symptomatic menopausal women from the most effective treatment available for these symptoms. The following evidence-based facts are important in revoking this decision:

1. No other medications on the Beers List are considered inappropriate because they "lack protection." The Beers List is designed to provide a "grading of the evidence on drug-related problems and adverse events in older adults." **Declaring a medication "high risk" because it does not protect against adverse outcomes that would accrue to those who do not take these medications is neither sensible nor consistent with the objective of the Beers List.**
2. The carcinogenic potential of hormone therapy is confined to the breast and to the use of estrogen with progestin in women with an intact uterus. **When appropriately used, the risk of endometrial cancer does not differ from background rates or is reduced.<sup>1</sup>**
3. Although the Beers Criteria do not specifically review potential thromboembolic risks associated with hormone therapy use, it is important to note that risks appear to differ by dose, formulation, and route of administration. For example, risks were increased for women who used conjugated equine estrogen plus medroxyprogesterone acetate in the Women's Health Initiative (WHI) trial,<sup>2</sup> and there was a smaller increase in risk in women with hysterectomy who were randomized to conjugated equine estrogens alone.<sup>3</sup> **Additionally, there is fair evidence based on observational studies that both oral estradiol<sup>4</sup> and nonoral estradiol<sup>5</sup> are NOT associated with the same level of risk, and these are the preferred agents as described in the NAMS 2017 Position Statement on Hormone Therapy<sup>6</sup> and the American College of Obstetricians and Gynecologists Practice Bulletin #141.<sup>7</sup>**

4. The global index for the WHI achieved statistical significance for harm only in the women taking estrogen plus progestin with an intact uterus,<sup>3</sup> not for women with hysterectomy who received estrogen alone.<sup>3</sup> However, two follow-up studies by WHI investigator Dr. JoAnn Manson continue to verify a neutral overall health effect of the 6- to 7-year hormone intervention in the WHI trials,<sup>8,9</sup> and an international Cochrane review confirms a lack of increased mortality risk associated with hormone therapy based on international studies, including the WHI.<sup>10</sup>
5. The Beers List ignores the beneficial effects of hormone therapy with estrogen and progestin against which the risks described must be balanced. **Because the Beers List is used as a criterion for denial of coverage by most health insurance providers, it does a grave disservice to women to deny them relief of menopause symptoms, all the more so because the nonhormone alternatives for menopause symptoms are inferior to estrogen in their effectiveness. Notably, the average duration of frequent or moderate to severe menopause vasomotor symptoms is 9 to 10 years, and 25% of women experience them well into their 60s and beyond.**

We therefore respectfully urge HEDIS to reconsider this adverse designation of hormone therapy for menopausal women because it is not current, is not accurate, and ultimately harms women by failing to treat bothersome menopause symptoms, which are exceedingly common and often long lasting.<sup>11</sup>

## REFERENCES

1. Brinton LA, Felix AS. Menopausal hormone therapy and risk of endometrial cancer. *J Steroid Biochem Mol Biol.* 2014;142:83-89.
2. Rossouw JE, Anderson GL, Prentice RL, et al; 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.
3. Anderson GL, Limacher M, Assaf AR, et al; Women's Health Initiative Steering Committee. Effects of conjugated equine estrogen in postmenopausal women with hysterectomy: the Women's Health Initiative randomized controlled trial. *JAMA.* 2004;291(14):1701-1712.
4. Vinogradova Y, Coupland C, Hippisley-Cox J. Use of hormone replacement therapy and risk of venous thromboembolism: nested case-control studies using the QRResearch and CPRD databases. *BMJ.* 2019;364:k4810.
5. American College of Obstetricians and Gynecologists. ACOG committee opinion no. 556: postmenopausal estrogen therapy: route of administration and risk of venous thromboembolism. *Obstet Gynecol.* 2013;121(4):887-890.
6. The NAMS 2017 Hormone Therapy Position Statement Advisory Panel. The 2017 hormone therapy position statement of The North American Menopause Society. *Menopause.* 2017;24(7):728-753.
7. ACOG Practice Bulletin No. 141: management of menopausal symptoms. *Obstet Gynecol.* 2014;123(1):202-216. Erratum in: Practice Bulletin No.141: management of menopausal symptoms: correction. *Obstet Gynecol.* 2016;127(1):166; Practice Bulletin No.141: management of menopausal symptoms: correction. *Obstet Gynecol.* 2018;131(3):604.
8. Manson JE, Chlebowski RT, Stefanick ML, et al. Menopausal hormone therapy and health outcomes during the intervention and extended poststopping phases of the Women's Health Initiative randomized trials. *JAMA.* 2013;310(13):1353-1368.
9. Manson JE, Aragaki AK, Rossouw JE, et al; WHI Investigators. 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.
10. Marjoribanks J, Farquhar C, Roberts H, Lethaby A, Lee J. Long-term hormone therapy for perimenopausal and postmenopausal women. *Cochrane Database Syst Rev.* 2017;1:CD004143.
11. Avis NE, Crawford SL, Greendale G, et al; Study of Women's Health Across the Nation. Duration of menopausal vasomotor symptoms over the menopause transition. *JAMA Intern Med.* 2015;175(4):531-539.

## **Directions to Submit a Comment**

This is an important issue for midlife women, and we encourage you to have your voice heard by submitting a comment to the NCQA. Please feel free to use the information in the NAMS comment for your own submission.

Submit your comment today! [\[https://my.ncqa.org/?ReturnUrl=%2fPublicComments\]](https://my.ncqa.org/?ReturnUrl=%2fPublicComments)

1. Click on “Log In with Single Sign In”
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3. Fill out your personal information and submit
4. Click on “Public Comments” at the bottom of the screen
5. Click “add comment” on the top right
6. Under product, select “HEDIS public comment”
7. Under topic, select “proposed changes to existing measures”
8. Under element, select “Use of high-risk medications in older adults”
9. Under support type, select “support with modifications”
10. Paste your comment in the box and hit submit