ISSWSH Menopause Panel

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Disclosures

Estrogen use after age 65

Exhibit A:

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2300 Main Street CA134-0404
Irvine, CA 92614

February 13, 2015

To: MD
Fax:
Re: **Geriatric RxMonitor Program**

Dear MD:

As the pharmacy prescription plan manager for UnitedHealthcare, OptumRx administers the Geriatric RxMonitor program to reduce the use of high-risk medications by seniors 65 and older and promote the safe use of medications.

The enclosed report identifies your patient who we insure as receiving a medication(s) that is potentially inappropriate according to the Medicare 5-Star Health and Drug Plan Quality and Performance Rating and Health Effectiveness Data and Information Set's (HEDIS) Use of High-Risk Medications in the Elderly quality measure.

Knowing that you take a number of variables into account that are not available to us, if you have already identified this issue, please disregard this notice and continue to monitor the member for any potential issues. You do not need to respond to this letter.

If you have any questions, please contact OptumRx at **1-877-399-0329**. Thank you.

Sincerely,

UnitedHealthcare®

Enclosure

Estrogen use after age 65 – The Beers List

- The Beers list is a list of drugs considered potentially harmful after age 65 – it includes systemic estrogen therapy
- HEDIS has adopted the Beers List as a quality measure
- HEDIS (Healthcare Effectiveness Data and Information Set) is a tool for healthplan evaluations used by more than 90% of US healthplans, including Medicare
- Clinicians receive letters from insurance companies informing them that they are using a medication that is potentially inappropriate

Beers MH. *Arch Intern Med* 1991;151:1825-32.

AGS. *J Am Geriatr Soc* 2012;60:616-31.

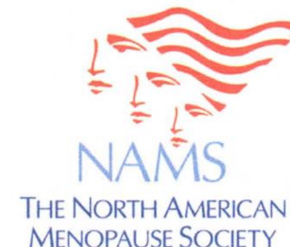
Estrogen use after age 65 and the Beers List

NAMS STATEMENT

The North American Menopause Society Statement on Continuing Use of Systemic Hormone Therapy After Age 65

The 2012 Hormone Therapy Position Statement of The North American Menopause Society (NAMS) states that hormone therapy (HT) is the most effective treatment for symptoms of menopause.[1] To maximize safety, the initiation of HT should be considered for healthy symptomatic women who are within 10 years of menopause or aged younger than 60 years and who do not have contraindications to use of HT. Contraindications are well established and should be considered in making this decision. However, vasomotor symptoms persist for an average of 7.4 years and for more than a decade in many women.[2] Moderate to severe vasomotor symptoms have been documented in 42% of women aged 60 to 65 years.[3] Thus, many women will continue to have vasomotor symptoms after age 65, and these symptoms can disrupt sleep and adversely affect health and quality of life.[2-4]

Provided that the woman has been advised of the



Menopause 2015;22:693.

REFERENCES

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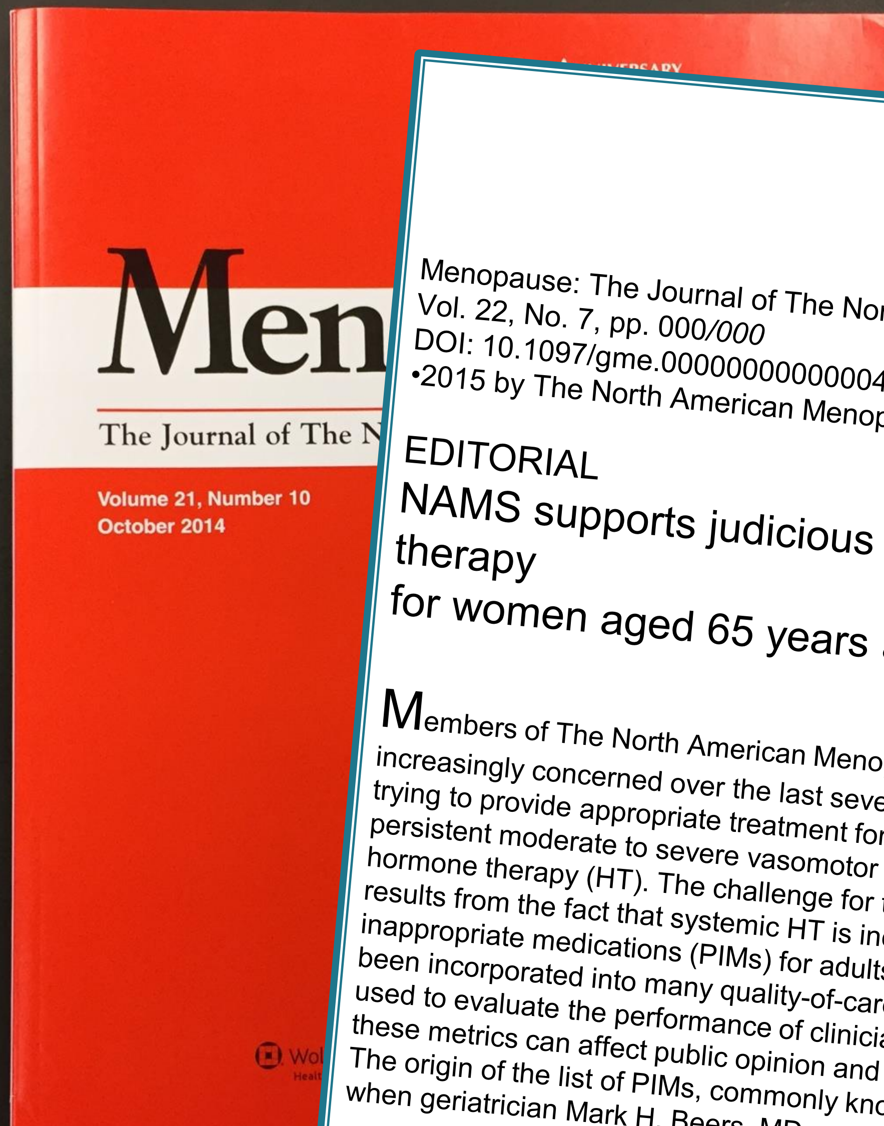
Provided that the woman has been advised of the increase in risks associated with continuing HT beyond age 60 and has clinical supervision, extending HT use with the lowest effective dose is acceptable under some circumstances, such as for the woman who has persistent bothersome menopausal symptoms and for whom her clinician has determined that the benefits of menopause symptom relief outweigh the risks. Use of HT should be individualized and not discontinued solely based on a woman's age.[5] The decision to continue or discontinue HT should be made jointly by the woman and her healthcare provider.

REFER

1. The 2012 Menopause
2. Avis NE, Across the toms over t
3. Gartoulla P and sexual *Menopause*
4. Kaunitz A *Menopause*
5. ACOG Pra *Obstet Gyn*

Menopause 2015;22:693.

NAMS supports judicious use…



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EDITORIAL

NAMS supports judicious use of systemic hormone therapy
for women aged 65 years and older

Members of The North American Menopause Society (NAMS) have become increasingly concerned over the last several years about the challenges they fac trying to provide appropriate treatment for older postmenopausal women who ha persistent moderate to severe vasomotor symptoms or other indications for syste hormone therapy (HT). The challenge for these and other clinicians results from the fact that systemic HT is included on the list of potentially inappropriate medications (PIMs) for adults aged older than 65 years. This list has been incorporated into many quality-of-care measures, and these metrics are bei used to evaluate the performance of clinicians and healthcare systems. Scores fro these metrics can affect public opinion and even credentialing of healthcare syster The origin of the list of PIMs, commonly known as the Beers list, when geriatrician Mark H.

Estrogen use after age 65 – The Beers List

AGS published their 2015 update of the Beers list online –

- Google Beers List 2015
- "Get PDF – Wiley Online Library"

AGS. *J Am Geriatr Soc* 2015 Online

NAMS Effort to Change Label for Low Dose Vaginal Estrogen

- Arranged conference call with FDA re Boxed Warning
- Published editorial explaining rationale for label change
- FDA held public hearing in November, 2015

Issues to Consider with Use of Vaginal Estrogen

- **No RCT safety data beyond 1 year**

- **Postmenopausal endogenous estrogen levels:**

  Higher levels are associated

  Endometrial cancer

  Breast Cancer

  Stroke

  Fewer fractures

Issues to Consider with Use of Vaginal Estrogen

- ❖ Uterine cancer is the most common gynecologic cancer
- ❖ Main risk factor: excess of endogenous or exogenous estrogen
- ❖ Both dose and duration dependent.
- ❖ Average age 61, peak ages 50-64 (43%)
- ❖ With 5 or more yrs of systemic use: 10-30 fold increased risk
- ❖ Increased risk persists more than 10 years after 1 year of use
- ❖ Possibility of first pass uterine effect
- ❖ Estrogen is on the National Toxicology Program list of known human carcinogens.
- ❖ Women in RCTs were screened with endometrial biopsy/sono

Issues to Consider with Use of Vaginal Estrogen (contd)

- How to define low dose vaginal estrogen
- Low dose vaginal tablet 10 mcg twice a week delivers 20 mcg/wk
- Low dose vaginal ring 7.5 mcg/d delivers 52.5 mcg/wk

Issues to Consider with Use of Vaginal Estrogen (contd)

- Breast cancer therapy often hormonal (anti-estrogen)
- Aromatase inhibitors (AIs)are thought to work by suppressing estrogen levels
- AIs with greater estrogen suppression have better breast cancer results