

Effective Health Care Hormone Therapy for Treatment of Menopausal Symptoms Nomination Summary Document

## **Results of Topic Selection Process & Next Steps**

- Hormone therapy for the treatment of menopausal symptoms will go forward for refinement as a systematic review. The scope of this topic, including populations, interventions, comparators, and outcomes, will be further developed in the refinement phase.
- When key questions have been drafted, they will be posted on the AHRQ Web site and open for public comment. To sign up for notification when this and other Effective Health Care (EHC) Program topics are posted for public comment, please go to <a href="http://effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/">http://effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/</a>.

## **Topic Description**

Nominator:Public policy maker/payerNomination<br/>Summary:The nominator is interested in the comparative effectiveness of different hormone<br/>therapy preparations used by postmenopausal women and women in the menopausal<br/>transition stage for the treatment of symptoms of menopause and prevention of low<br/>bone density and fractures. The nominator also questions the comparative harms of<br/>these treatments for both short-term (<5 years) and long-term use. Finally, the<br/>nominator is interested in whether there are subgroups of patients for whom one<br/>hormone therapy treatment may be more effective or have fewer adverse events.Key Questions1. What is the comparative effectiveness of different hormone therapy preparations

- from Nominator: when used by postmenopausal women or women in the menopausal transition stage for reducing symptoms of menopause: hot flashes/flushes, sleep disturbances/night sweats, mood changes (depression), urogenital atrophy, sexual function, and quality-of-life measures? Are there differences between estrogen replacement products and low-dose estrogen oral contraceptives?
  - 2. What is the comparative effectiveness of different hormone therapy preparations when used by postmenopausal women or women in the menopausal transition stage for preventing low bone density and fractures? Are there differences between estrogen replacement products and low-dose estrogen oral contraceptives?
  - **3.** What are the comparative harms of different hormone therapy preparations for short-term use (<5 years)? Are there differences between estrogen replacement products and low-dose estrogen oral contraceptives?
  - **4.** What are the comparative harms of different hormone therapy preparations for long-term use (5 or more years)? Are there differences between estrogen replacement

products and low-dose estrogen oral contraceptives?

**5.** Are there subgroups of patients based on demographics, other medications, comorbidities, length of use, or initiation of use relative to onset of menopause, for which one medication, preparation, or estrogen dose is more effective or associated with fewer adverse effects?

## Considerations

- The topic meets all EHC Program selection criteria. (For more information, see <a href="http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/">http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/</a>.)
- Hormone replacement therapy (HRT) is used often in clinical practice for the treatment of menopausal symptoms (e.g., hot flashes). However, there remains a lot of confusion among practitioners, patients, and policy makers surrounding the use of HRT. There are many issues that could potentially be informed by an evidence review on this subject regarding dosing, routes of administration, and subpopulations (e.g., women with cardiovascular-related health issues).
- The refinement phase will consider scoping issues such as the potential inclusion of Tibolone, complementary and alternative (CAM) therapies, and other classes of pharmaceuticals that may treat the symptoms of menopause (e.g., antidepressants) as potential comparators to HRT.