



from JoAnn V. Pinkerton, MD, NCMP, Executive Director



## NAMS Recognizes and Commends CMS Clarification of GSM Drug Coverage

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The North American Menopause Society (NAMS) joins The International Society for the Study of Women's Sexual Health, the American College of Obstetricians and Gynecologists, and other major organizations in recognizing the Centers for Medicare and Medicaid Services (CMS) for acting on a major health concern for postmenopausal women by no longer excluding from Medicare Part D coverage drugs for the treatment of moderate to severe dyspareunia due to menopause when used consistent with this labeling under their "Prescription Drug Benefits" section 1860D-2(e)(2)(A) of the Social Security Act. Postmenopausal women can now receive access to newer, tested, and effective FDA-approved therapies to relieve symptoms and signs of vulvovaginal atrophy (VVA), a component of the genitourinary syndrome of menopause (GSM).

Dyspareunia in postmenopausal women should not be considered sexual dysfunction but rather the most common presenting symptom of GSM, a chronic, progressive medical condition that is the result of lowered estrogen levels in vaginal and urogenital tissue after menopause, resulting in thinning of the vaginal tissues. At least 50% to 70% of the approximately 64 million postmenopausal women in the United States will experience symptoms of GSM.

In addition to this important issue, NAMS has enacted additional multidisciplinary advocacy efforts, including

- A Citizen's Petition to FDA requesting modification of the labeling for low-dose vaginal estrogen products approved for treating symptoms of VVA that removes the boxed warning that frightens women and their providers. NAMS recommends a different product label that reflects evidence-based information for low-dose vaginal estrogen products and includes the fact that genital bleeding may be a sign of endometrial cancer and that women with estrogen-sensitive breast cancer consult with their oncologists before using the product.
- A request to FDA to include compounded hormones used for menopausal women in the "difficult to compound" class. There are many available FDA-approved hormone therapy products that have been tested for safety and efficacy. There is limited rationale for the use of nonapproved products, unless there are allergies to approved products or a need for a dose or formulation that is currently unavailable. The lack of adequate regulatory oversight leads to concerns about quality, sterility, bioavailability, and over- or underdosing. Patient safety is impaired by the lack of package inserts, labels, or standard warnings.

NAMS remains committed to improving women's health and access to healthcare by joining forces in advocating for women at menopause and beyond. NAMS commends CMS on its decision to provide coverage for women with postmenopausal dyspareunia, which will improve urogenital health and improve their quality of life.

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