Medica® (formerly WellFirst Health)

Medica (formerly WellFirst Health) Health Plan by Coverage Policy

Policy Name:	**Compounded Bio-Identical Hormone Replacement Therapy (BHRT)**
Effective Date:	**5/1/2025**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member's plan document for specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Compounded Bio-Identical hormone products and associated medical services are investigative and therefore NOT COVERED. For a list of COVERED FDA- approved bioidentical hormone replacement therapies through the pharmacy benefit, refer to the Medica PDL: https://www.medica.com/providers/pharmacy

Description

Bio-identical hormone replacement therapy, often referred to as "natural" hormone replacement therapy is used to treat hormone imbalances in men and women. Low or unbalanced hormone levels are attributed to causing a wide range of symptoms including, but not limited to, loss of energy, hot flashes, fibromyalgia, memory lapse, and depression. The use of bio-identical hormones has gained popularity over the last ten years which may be attributable to the publication of the results of the Women's Health Initiative and direct to consumer advertising promoting these compounded preparations as safe and effective alternatives to conventional therapy. The Women's Health Initiative found that women treated with traditional (synthetic) estrogen and progesterone had a greater incidence of coronary heart disease, breast cancer, stroke, and pulmonary embolism compared to those treated with placebo. Bio-identical hormones are compounded from plant sources and are purported to be exactly the same hormones present in the human body, thus safer than standard prescription synthetic hormones. Prescriptions for these products are often written by alternative medicine providers in individualized doses/regimens and are often prepared by and obtained from compounding pharmacies. Proponents of BHRT have argued that such use may even result in the decreased need for other medications such as those that treat osteoporosis, diabetes, and erectile dysfunction and possibly reduce one's risk of developing breast cancer, heart attacks, cancer and Alzheimer's disease. This policy applies to bio-identical hormone replacement products that are compounded. This policy excludes Testopel® (testosterone pellets), which is an FDA approved formulation for use in males only.

The evidence-based medical community contends that the risks involved in prescribing a hormonal product depends on its chemical composition and biochemical properties, not on how it was made. The American College of Obstetricians and Gynecologists (ACOG) warned against use of bio-identical hormone replacement products in a statement reaffirmed in 2023. ACOG stated:

- There is a lack of high-quality data on the safety and efficacy of custom-compounded bioidentical hormone therapy for

the management of menopausal symptoms.

- Compounded bioidentical menopausal hormone therapy should not be prescribed routinely when FDA-approved formulations exist.
- Most compounded products have not undergone rigorous clinical testing for either safety or efficacy. There are also concerns regarding their purity, potency, and quality.
- An oral capsule containing 1 mg 17 beta-estradiol (E2) combined with 100 mg micronized progesterone (MP; both bioidentical) is effective and approved for the treatment of hot flashes; it is also endometrial protective.
- The FDA requires manufacturers of FDA-approved products that contain estrogen and progestin to include a black box warning that reflects the findings of the Women's Health Initiative. However, compounded products (including "bio-identical hormones") are not approved by the FDA and have been exempt from having to provide patient package inserts that contain warnings and contraindications for estrogens and progestins.
- Given the lack of well-designed and well-conducted clinical trials of these compounded hormones, all of them should be considered to have the same safety issues as those hormone products that are approved by the FDA and may also have additional risks unique to the compounding process.

The North American Menopause Society in 2022 issued an updated position statement regarding the use of bioidentical hormone replacement therapy. Key points include:

- Compounded bioidentical hormone therapy presents safety concerns such as minimal government regulation and monitoring, overdosing, underdosing, presence of impurities, or lack of sterility, lack of scientific efficacy and safety data, and lack of a label outlining risks.
- Only consider compounded HT if women cannot tolerate government approved products or dose/formulation is not available in government approved products.

The FDA has taken action against marketers of compounded bio-identical hormones, fearing their claims mislead the general public as well as health care professionals, giving them a false sense of assurance about using potentially dangerous hormone products. In January 2008, the FDA ordered seven compounding pharmacies to stop making "false and misleading" claims about custom-made bio-identical hormones for menopausal symptoms. Though thousands of pharmacies nationwide custom compound bio-identical hormone products, the FDA cited three reasons for targeting these specific pharmacies. These reasons include business claims that their mixtures could prevent or treat illnesses such as Alzheimer's disease, stroke and cancer; claims that pharmacy mixtures were superior to approved commercial drugs; and that these pharmacies used the hormone estriol, a weak estrogen that isn't FDA-approved.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s).

Original Effective Date: 11/17/2011

Re-Review Date(s): 10/30/2014, 9/11/2017
06/22/2021, 2/27/24, 4/17/25