

VHA Office of Integrated Veteran Care
Clinical Determination and Indication
Compounded Bioidentical Hormone Therapy

CDI Number: 00050

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I. Disclaimer

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgment when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

II. Clinical Determinations and Indications

a. Indications for Compounded Bioidentical Hormone Therapy

Compounded bioidentical hormone therapy (cBHT) is considered **investigational and experimental** for the following example indications, including but not limited to the following:

- Treating symptoms of menopause
- Regulating the menstrual cycle
- Supporting fertility
- Skin rejuvenation to reduce wrinkles and enhance muscle tone
- Building muscle mass
- Low libido

There is insufficient evidence from peer-reviewed medical literature to support the safety and efficacy of cBHT. Therefore, cBHT is considered **not medically necessary**.

III. Background and Supporting Information

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determinations for medical necessity and alignment with generally accepted standards of medical practice.

a. Background Information

Endocrine glands produce hormones that carry messenger molecules through the bloodstream to organs, muscles, skin, and other tissues to coordinate distinct

functions within the body. Adequate hormone levels are essential for one's health and can decrease with age. Even a slight imbalance of hormones can cause symptoms that interfere with a person's physiology and daily activities.

Bioidentical hormones are manufactured products that replicate the function of hormones made by the endocrine glands. Individuals may take bioidentical hormones to increase levels within the body to alleviate symptoms caused by low hormone levels. The most common use of bioidentical hormone therapy is treating symptoms from perimenopause or menopause. These prescription forms of bioidentical hormones are manufactured by drug companies and have been approved by the U.S. Food and Drug Administration (FDA), meaning they have been evaluated for safety and efficacy.

Compounded bioidentical hormones are custom made or compounded by pharmacists based on prescriptions written by a physician. These products are typically prescribed by alternative medicine providers. These compounded forms have not been tested and approved by the FDA. While marketers may claim compounded hormones offer advantages over traditional hormone therapy, there is no evidence to support these claims.

b. Research, Clinical Trials, and Evidence Summaries

There is insufficient evidence from peer-reviewed medical literature to support the safety and efficacy of compounded bioidentical hormone therapy (cBHT).

The American College of Obstetricians and Gynecologists (ACOG) issued consensus recommendations in 2023 against the use of compounded bioidentical hormone replacement products. The recommendation 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." Additionally, ACOG stated that there are no FDA-approved testosterone formulations for the management of menopausal symptoms.

An advisory panel of clinicians and research experts in the field of women's health and menopause updated the 2017 hormone therapy position statement of The North American Menopause Society (NAMS) in 2022. The NAMS position on cBHT is unchanged and states, "Compounded bioidentical hormone therapy presents safety concerns, such as minimal government regulation and monitoring, overdosing or underdosing, presence of impurities or lack of sterility, lack of scientific efficacy and safety data, and lack of a label outlining risks."

A 2020 consensus study report published by the National Academies of Sciences, Engineering, and Medicine concluded there is insufficient evidence to support the use of cBHT for the treatment of menopause and male hypogonadism symptoms. It also outlines recommendations to restrict the use of cBHT preparations and improve education for prescribers and pharmacists who market, prescribe, compound, and dispense cBHT products.

The 2019 position statement from the Endocrine Society supports FDA-regulated hormones and is concerned that there is potentially misleading and/or false information about the benefits and risks of compounded bioidentical hormones being provided to patients.

c. Medicare Coverage Determinations

There are no available Medicare coverage determinations for cBHT. VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

d. Health Care Procedural Coding Information

There are no CPT®/HCPCS codes listed in this section. Inclusion or exclusion of a code does not constitute or imply VA coverage or provider reimbursement. The list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than CDI updates. Please refer to section II.a. in this document to review indications and clinical criteria for medical necessity.

IV. Definitions

Term	Definition
Bioidentical	Hormones that are chemically and structurally identical to those produced by the human body
Hypogonadism	A condition where an individual's testes or ovaries produce insufficient quantities of sex steroid hormones
Menopause	The age-related cessation of menstrual cycles due to ovarian function, resulting in female hypogonadism. The decline in estrogen levels may produce symptoms such as hot flashes, night sweats, sleeplessness, low energy, and mood swings
Perimenopause	The transition to menopause, characterized by reduced frequency and irregularity of menses occurring over the 12 months after a menstrual cycle

V. References

American College of Obstetricians and Gynecologists (2023) Committee on Clinical Consensus—Gynecology: Compounded bioidentical menopausal hormone therapy. <https://www.acog.org/clinical/clinical-guidance/clinical-consensus/articles/2023/11/compounded-bioidentical-menopausal-hormone-therapy>

Compounded Bioidentical Hormone Therapy. (2019) An Endocrine Society Position Statement. <https://www.endocrine.org/advocacy/position-statements/compounded-bioidentical-hormone-therapy#:~:text=them%20are%20made.-,POSITIONS,structure%20or%20method%20of%20manufacture>

Craven, J. (2024, March 20). FDA proposes rule for difficult-to-compound drugs, drug categories. Regulatory Focus. <https://www.raps.org/news-and-articles/news-articles/2024/3/fda-proposes-rule-for-difficult-to-compound-drugs>

National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on the Clinical Utility of Treating Patients with Compounded Bioidentical Hormone Replacement Therapy, Jackson, L. M., Parker, R. M., & Mattison, D. R. (Eds.). (2020). The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use. National Academies Press (US). <https://nap.nationalacademies.org/catalog/25791/the-clinical-utility-of-compounded-bioidentical-hormone-therapy-a-review>

“The 2022 Hormone Therapy Position Statement of The North American Menopause Society” Advisory Panel (2022). The 2022 hormone therapy position statement of The North American Menopause Society. Menopause (New York, N.Y.), 29(7), 767–794. <https://doi.org/10.1097/GME.0000000000002028>

VI. CDI History/Revision Information

Date	Summary of Update(s)
09/17/2025	<ul style="list-style-type: none"> <li data-bbox="516 1539 1209 1581">New investigational/experimental CDI created