



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA  
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 09/17/24  
LAST REVIEW DATE: 09/17/24  
CURRENT EFFECTIVE DATE: 09/17/24  
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NEXT ANNUAL REVIEW DATE: 3RD QTR 2025

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## HORMONE THERAPY

- Hormone Pellet Therapy
- Compounded Bioidentical Hormone Therapy

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Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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### Description:

Hormone pellets are implanted under the skin through a small incision to deliver hormones into the bloodstream. The procedure is usually performed in the physician's office using a local anesthetic.

Implantable hormone pellets include the following:

- Estradiol
- Estrogen
- Estrogen compounded with testosterone
- Testosterone

Bioidentical hormones are substances that have the exact same chemical composition as hormones produced in the human body. Many FDA-approved hormone preparations are bioidentical. However, the term is more commonly used to describe compounded hormone formulations containing estrogens, progesterone, and/or testosterone that are not FDA-approved. These formulations are often promoted as safer or more effective alternatives to manufactured FDA-approved hormone therapies. Compounded bioidentical hormone formulations are not subject to FDA regulations or oversight and can be inconsistent in dose and purity.

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### Criteria:

- Subcutaneous hormone pellet implants are considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

These formulations include, *but are not limited to*:

- Compounded hormone pellets (e.g. compounded testosterone, estrogen, or progesterone pellets)
- All non-FDA approved commercially available hormone pellet products

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## HORMONE THERAPY

- Compounded bioidentical hormone replacement therapy is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

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### Resources:

Literature reviewed 09/17/24. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 09/20/23 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. American College of Obstetricians and Gynecologists. Compounded Bioidentical Menopausal Hormone Therapy: ACOG Clinical Consensus No. 6. *Obstet Gynecol*. Nov 1 2023;142(5):1266-1273. doi:10.1097/AOG.0000000000005395
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10. Donovitz G, Cotten M. Breast Cancer Incidence Reduction in Women Treated with Subcutaneous Testosterone: Testosterone Therapy and Breast Cancer Incidence Study. *Eur J Breast Health*. Apr 2021;17(2):150-156. doi:10.4274/ejbh.galenos.2021.6213
11. Donovitz GS. Low complication rates of testosterone and estradiol implants for androgen and estrogen replacement therapy in over 1 million procedures. *Ther Adv Endocrinol Metab*. 2021;12:20420188211015238. doi:10.1177/20420188211015238
12. Donovitz GS. A Personal Prospective on Testosterone Therapy in Women-What We Know in 2022. *J Pers Med*. Jul 22 2022;12(8)doi:10.3390/jpm12081194
13. Dorr B, Abdelaziz A, Karram M. Subcutaneous testosterone pellet therapy for reversal of male osteoporosis: a review and case report. *Aging Male*. Dec 2023;26(1):2181953. doi:10.1080/13685538.2023.2181953
14. Endocrine Society. Position Statement: Compounded Bioidentical Hormone Therapy. October 2, 2019. Accessed August 15, 2024. <https://www.endocrine.org/advocacy/position-statements/compounded-bioidentical-hormone-therapy>
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### Coding:

CPT: 11980, 17999

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### History:

| <u>History:</u>             | <u>Date:</u> | <u>Activity:</u>      |
|-----------------------------|--------------|-----------------------|
| Medical Policy Panel        | 09/17/24     | Approved guideline    |
| Medical Director (Dr. Raja) | 08/15/24     | Review with revisions |
| Clinical Pharmacist         | 08/14/24     | Review with revisions |

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### Policy Revisions:



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### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilínígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíłkídkgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíłkídkgo beehaz'áanii hółqo díí t'áa hazaadk'ehjí háká a'doowolgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíłnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

