Medical Coverage Policy | Salivary Estriol as Risk Predictor for Preterm Labor and Management of Menopause and/or Aging

EFFECTIVE DATE: 12|18|2003
POLICY LAST REVIEWED: 07|01|2026

OVERVIEW

Salivary tests are available for a number of hormones. Salivary hormone tests include but are not limited to estrogens, progesterone, testosterone, melatonin, cortisol, and dehydroepiandrosterone (DHEA). A number of salivary tests are available to consumers over the Internet without a physician's prescription. The results of these tests are purportedly used to determine the need for prescriptions for different hormones, vitamins, and herbs that are said to help in the management of menopause and aging.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

The use of salivary hormone testing is not covered for Medicare Advantage Plans as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

The use of salivary hormone testing is not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes.

Note: Laboratories are not allowed to obtain clinical authorization or participate in the authorization process on behalf of the ordering physician. Only the ordering physician shall be involved in the authorization, appeal or other administrative processes related to prior authorization/medical necessity.

In no circumstance shall a laboratory or a physician/provider use a representative of a laboratory or anyone with a relationship to a laboratory and/or a third party to obtain authorization on behalf of the ordering physician, to facilitate any portion of the authorization process or any subsequent appeal of a claim where the authorization process was not followed and/or a denial for clinical appropriateness was issued, including any element of the preparation of necessary documentation of clinical appropriateness. If a laboratory or a third party is found to be supporting any portion of the authorization process, BCBSRI will deem the action a violation of this policy and severe action will be taken up to and including termination from the BCBSRI provider network. If a laboratory provides a laboratory service that has not been authorized, the service will be denied as the financial liability of the participating laboratory and may not be billed to the member.

Commercial Products

Some genetic testing services are not covered and a contract exclusion for any self-funded group that has excluded the expanded coverage of biomarker testing related to the state mandate, R.I.G.L. **§27-19-81** described in the Biomarker Testing Mandate policy. For these groups, a list of which genetic testing services are covered with prior authorization, are not medically necessary or are not covered because they are a contract exclusion can be found in the Coding section of the Genetic Testing Services or Proprietary Laboratory Analyses policies. Please refer to the appropriate Benefit Booklet to determine whether the member's plan has customized benefit coverage. Please refer to the list of Related Policies for more information.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Salivary Testing for Management of Menopause and/or Aging

The scientific validity of salivary hormone levels in order to diagnose or monitor hormone deficiency has not been established. There are no published studies that document the validity of using salivary hormone testing to diagnose, treat, or monitor menopause or aging. The American College of Obstetricians and Gynecologists (ACOG), the U.S. Food and Drug Administration (FDA), the North American Menopause Society (NAMS), the Institute for Clinical Systems Improvement, and the American Association of Clinical Endocrinologists (AACE) have all issued statements that address the questionable validity of salivary hormone testing:

- ACOG's Committee Opinion #532, *Compounded Bioidentical Menopausal Hormone Therapy,* Data on the interpretation of adjunct hormone tests for prescribing and dosing compounded bioidentical menopausal hormone therapy are limited; thus, these tests are not recommended for these indications…Although proponents claim that salivary testing can help tailor hormone therapy, salivary testing does not offer accurate or precise assessment of hormone levels. Currently, there are no FDA-approved salivary or urinary tests for steroid hormone measurement. (ACOG 2026).
- The FDA states that "there is no scientific basis for using salivary testing to adjust hormone levels."
- NAMS indicates in their *2022 Hormone Therapy Position Statement of The North American Menopause Society* "Compounded bioidentical hormone therapy has been prescribed or dosed on the basis of serum, salivary, or urine hormone testing; however, the use of such testing to guide hormone therapy dosing is considered unreliable because of differences in hormone pharmacokinetics and absorption, diurnal variation, and interindividual and intraindividual variability….. Salivary and urine hormone testing to determine dosing are unreliable and not recommended. Serum hormone testing is rarely needed." (NAMS 2022).
- The Institute for Clinical Systems Improvement concluded in its 2008 assessment: "Currently, there is insufficient evidence in the published scientific literature to permit conclusions concerning the use of salivary hormone testing for the diagnosis, treatment, or monitoring of menopause and aging." (ICSI 2008).
- The AACE's *Reproductive Medicine Committee 2017 Position Statement on Bioidential Hormones* states "individualized dosing frequently based upon unproven testing methods such as salivary assays, which has not been validated."

Salivary Testing for Preterm Birth

Preterm birth is considered a major healthcare problem worldwide. The National Center for Health Statistics reports that approximately 11% of the estimated 4 million births in the United States annually are preterm, incurring significant morbidity and mortality. Therefore, identification of women at risk for preterm labor has been a research focus for many years, with the hope that early intervention can prevent the progression from preterm labor to preterm birth. Current techniques include a scoring system based on a patient's past medical history (the Creasy system), home uterine activity monitoring, and measurements of fetal fibronectin collected on a cervical swab. It has also been observed that salivary estriol levels surge several weeks before the onset of spontaneous preterm labor. Therefore, measurement of salivary estriol has been explored as a risk predictor for preterm labor. SalEst™ is a laboratory technique approved by the FDA for measuring salivary estriol as a risk assessment marker of preterm labor and delivery. The SalEst system is indicated for use every 1 to 2 weeks in pregnant women with singleton pregnancies between their 22nd and 36th weeks of pregnancy.

No clinical studies are available that demonstrate that treatment decisions based on salivary testing result in beneficial health outcomes, therefore Salivary Testing is considered not medically necessary as there is no proven efficacy.

CODING

Medicare Advantage Plans and Commercial Products

The following HCPCS code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

S3650 Saliva test, hormone level; during menopause

S3652 Saliva test, hormone level; to assess preterm labor risk

RELATED POLICIES

Biomarker Testing Mandate

PUBLISHED

Provider Update, September 2026
Provider Update, September 2025
Provider Update, October 2024
Provider Update, November 2023
Provider Update, December 2022

REFERENCES

1. Heine RP, McGregor JA, Dullien VK. Accuracy of salivary estriol testing compared to traditional risk factor assessment in predicting preterm birth. Am J Obstet Gynecol 1999;180(1 pt 3):S214-8.
2. Heine RP, McGregor JA, Goodwin TM et al. Serial salivary estriol to detect an increased risk of preterm birth. Obstet Gynecol 2000; 96(4):490-7.
3. American College of Obstetricians and Gynecologists (ACOG) press release. SalEst™ not recommended as a screening tool for predicting premature labor. Washington, DC; January 31, 2001.
4. The North American Menopause Society. (NAMS) What is Hormone Testing? http://www.menopause.org/publications/clinical-practice-materials/bioidentical-hormone-therapy/what-is-hormone-testing-
5. American Association of Clinical Endocrinologists (AACE) Reproductive Medicine Committee Position Statement on Bioidentical Hormones. https://www.aace.com/files/position-statements/aacebhstatement071507.pdf
6. American College of Obstetricians and Gynecologists' Committee on Clinical Consensus-Gynecology. (2023). Compounded Bioidentical Menopausal Hormone Therapy Clinical Consensus. In *www.acog.org*. American College of Obstetricians and Gynecologists. Retrieved July 1, 2025, from https://www.acog.org/-/media/project/acog/acogorg/clinical/files/clinical-consensus/articles/2023/11/compounded-bioidentical-menopausal-hormone-therapy.pdf
7. The 2022 Hormone Therapy Position Statement of The North American Menopause Society. (2022). Menopause: The Journal of the North American Menopause Society, 29(7), 767–794. https://www.menopause.org/docs/default-source/professional/nams-2022-hormone-therapy-position-statement.pdf
8. American College of Obstetricians and Gynecologists (ACOG). (2023). Compounded bioidentical menopausal hormone therapy.
9. North American Menopause Society (NAMS). (2022). Hormone therapy position statement.
10. American Association of Clinical Endocrinologists (AACE). (2017). Menopause guidelines.
11. U.S. Food and Drug Administration (FDA). (2025). Menopause and hormone therapy guidance.

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.