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 UPDATED: 10|06|2021

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 as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

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

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable Not covered/Not Medically Necessary 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 #322, *Compounded Biodentical Hormones,* indicates that salivary hormone testing is not meaningful because salivary hormone levels vary within each woman depending on her diet, the time of day, the specific hormone being tested, and other variables (ACOG 2005).
- The FDA states that "there is no scientific basis for using salivary testing to adjust hormone levels."
- NAMS indicates in their July 2008 *Position Statement: Estrogen and progestogen use in postmenopausal women* "salivary hormone testing is a procedure that has not been proven accurate or reliable." (NAMS 2008)

- 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 2007 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.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for the applicable Services Not Medically Necessary benefits/coverage.

CODING

Medicare Advantage Plans and Commercial Products

The following HCPCS code(s) are considered not medically necessary:

S3650 Saliva test, hormone level; during menopause
S3652 Saliva test, hormone level; to assess preterm labor risk

RELATED POLICIES

None

PUBLISHED

Provider Update, December 2021
Provider Update, January 2021
Provider Update, January 2020
Provider Update, November 2018
Provider Update, January 2018

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

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