

Medical Coverage Policy



Salivary Hormone Tests

Device/Equipment Drug Medical Surgery Test Other

Effective Date:	12/18/2003	Policy Last Updated:	5/23/2011
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Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Description:

Salivary Testing for Management of Menopause and/or Aging:

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.

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), US Food and Drug Administration (FDA), North American Menopause Society (NAMS), the Institute for Clinical Systems Improvement, and the American Association of Clinical Endocrinologists (AACE) have all issued statements which address the questionable validity of salivary hormone testing.

- ACOG's Committee Opinion #322, *Compounded Bioidentical 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 a birth that occurs before the 37th week of pregnancy. The cause of preterm labor is unknown in the majority of cases. Preterm birth is a worldwide healthcare issue that results in significant morbidity and mortality among preterm infants. Preterm labor occurs in approximately 11 percent of births in the United States.¹ Consequently, a number of different methods have been used to assist in identification of women who are at risk of preterm labor. Current techniques include using the Creasy System, which is based on a patient's past medical history, home uterine activity monitoring, and fetal fibronectin measurement. It has also been noted that salivary estriol levels rise before onset of preterm labor.

Estriol is an estrogen hormone that is produced by the placenta and plays a major role in labor leading to delivery. Estriol levels gradually increase in the first and second trimesters; the increase becomes more rapid in the third trimester, with a surge in estriol levels approximately two to three weeks prior to a full-term delivery. An elevation of estriol may also occur prior to a preterm birth. This increase is the basis of a screening test using salivary estriol levels to predict risk for preterm births.

However, there are no clinical studies that demonstrate that treatment decisions made based on salivary estriol testing result in beneficial health outcomes. The American College of Obstetricians and Gynecologists (ACOG) issued a press release² in January 2001 stating that "ACOG does not recommend salivary estriol testing because it has a high false-positive rate that could lead to unnecessary prenatal care interventions."

Medical Criteria:

Not applicable

Policy:

The use of salivary hormone testing to diagnose or monitor hormone deficiency is considered not medically necessary. There are no published clinical studies that document the validity of using salivary hormone testing to diagnose, treat, or monitor menopause or aging.

The use of salivary estriol levels as a predictor of preterm labor is considered not medically necessary. There are no published clinical studies that demonstrate that treatment decisions made based on the results of salivary estriol testing can be used to enhance patient management and improve beneficial health outcomes. The scientific

literature is inadequate to validate the clinical role of salivary estriol levels in the management of preterm labor.

Coverage:

Please refer to the appropriate member certificate/subscriber agreement for applicable not medically necessary service benefits/coverage.

Coding:

CPT code 82677 should not be used to report salivary hormone testing.

S3650 Saliva test, hormone level; during menopause (not medically necessary)

S3652 Saliva test, hormone level; to assess preterm labor risk (not medically necessary)

Also Known As:

SalEst™ System

Published:

Policy Update, March 2000

Provider Update, June 2008

Provider Update, July 2009

Provider Update, Dec 2010

Provider Update, Jul 2011

References:

¹Goldenberg, RL. High-risk Pregnancy Series: An Expert's View; The Management of Preterm Labor. American Journal of Obstetrics & Gynecology 2002; 100:1020-1037

²American College of Obstetricians and Gynecologists (ACOG) press release. "SalEst™ not recommended as a screening tool for predicting premature labor." Washington, DC; January 31, 2001.

American College of Obstetricians and Gynecologists (ACOG). Assessment of risk factors for preterm birth. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2001 Oct. 8 p. (ACOG practice bulletin; no. 31)

Blue Cross and Blue Shield Association . Salivary Estriol as Risk Predictor for Preterm Labor, Medical Policy Reference Manual, Policy# 02.04.11. 1:2004

AACE, American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Diagnosis and Treatment of Menopause. Endocr Pract, 2006. 12(3): p. 315-37.

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