Medical Coverage Policy | Salivary Hormone Tests

EFFECTIVE DATE: 12|18|2013
POLICY LAST UPDATED: 08|06|2013

OVERVIEW

Salivary tests are available for a number of hormones. Salivary hormone tests include but are not limited to estrogens, progesterone, testosterone, malatonin, 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

PRIOR AUTHORIZATION

Preauthorization is not required

POLICY STATEMENT

BlueCHiP for Medicare and Commercial

The use of salivary hormone testing is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

MEDICAL CRITERIA

None

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), US Food and Drug Administration (FDA), North American Menopause Society (NAMS), the Institute for Clinical Systems Improvement, and the American Association of Clinical Endorcrineologists (AACE) have all issued statements which addresse 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 (addressed in policy No. 4.01.09), and measurements of fetal fibronectin collected on a cervical swab (addressed in policy No. 2.04.03). 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 U.S. Food and Drug Administration (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

BlueCHiP for Medicare |
Commercial |

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

CODING

The following codes are not medically necessary:

S3650
S3652

RELATED POLICIES

None

PUBLISHED

Provider Update	Oct 2013
Provider Update	Sept 2012
Provider Update	July 2011
Provider Update	Dec 2010
Provider Update	Jul 2009
Provider Update	Jun 2008
Provider Update	Mar 2000

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

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS