



Louisiana

Salivary Hormone Testing

Policy # 00259

Original Effective Date: 07/21/2010

Current Effective Date: 09/19/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers salivary hormone testing to be **investigational**.*

Note: Salivary hormone tests include, but are not limited to:

- *Estrogen*
- *Progesterone*
- *Testosterone*
- *Cortisol*
- *Dehydroepiandrosterone (DHEA)*
- *Melatonin*

Background/Overview

Saliva is produced from the salivary glands located under the tongue and along the side of the mouth. The formation of saliva is dependent on the processes that actively pump electrolytes into the ducts and then allows for the diffusion of water into the duct by osmosis. Blood products, antibodies, small charged particles, and steroids or other neutral molecules enter the salivary ducts and mix with the electrolytes and water.

Bioavailable steroids (those not bound to the binding proteins in the blood) enter the saliva and are measurable, although it is a fraction of the serum levels.

Measurement of serum hormones is the gold standard measurement, and although salivary testing is available, correlations with the serum levels have been poor. Medical literature also fails to demonstrate that salivary tests appropriate for screening, diagnosing, or monitoring patients with menopause, osteoporosis, or other conditions of aging.

Interferences or disadvantages to the use of saliva testing for steroid hormones include; lack of standardization of the saliva testing packets, limitations due to technical resources and components necessary for a laboratory to accurately analyze saliva limit the number of lab that can successfully perform saliva testing. Contamination of saliva by blood from bleeding gums has been shown to effect hormone levels in the saliva. Additional limitations involve the interference by ingested foods and beverages, mucins in the saliva, presence of topical hormones, use of sublingual hormones and lack of proficiency oversight for saliva tasting.

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Rationale/Source

The Institute for Clinical Systems Improvement (2006) concluded: "Currently, there is insufficient evidence in the published literature to permit conclusions concerning the use of salivary hormone testing for the diagnosis, treatment or monitoring of menopause and aging".

Clinical practice guidelines from the North American menopause Society consider evidence to be insufficient to consider salivary hormone testing reliable. There are no published national practice guidelines that advocate the use of salivary hormone testing in the diagnosis, treatment or monitoring of menopause or aging.

Summary

There are currently no published studies documenting sensitivity, specificity and predictive values for any salivary hormone when used to diagnose, treat or monitor menopause or aging. In addition, there are no clinical trials that indicate the utility of salivary hormone testing to direct clinical treatment.

References

1. Grosch M. Current status of salivary hormone analysis. *Clin Chem.* 2008;54(11):1759-1769.
2. Zava D. Saliva Hormone Testing. *Townsend Letter for Doctors & Patients.* January 2004
3. Whembulua GL, Granger DA, Singer S, et al. Bacteria in oral mucosa and its effects on the measurement of cortisol, dehydroepiandrosterone, and testosterone in saliva. *Horm Behav.* 2006;49(4):478-83.
4. Boothby LA, Doering PL, Kipersztok S. Bioidentical hormone therapy: a review. *Menopause* 2004; 11(3):356-67.
5. The American Menopause Society. The role of testosterone therapy in postmenopausal women: position statement of the North American Menopause Society. *Menopause.* 2005;12(5):497/511.
6. Institute for Clinical Systems Improvement (ISCI). Menopause and hormone therapy (HT): collaborative decision-making and management. 2008;64:198
7. ACOG News Release: ACOG Reiterates Stance on So-Called "Bioidentical" Hormones. The American College of Obstetrics and Gynecologists; 2009 <http://www.acog.org/>.

Policy History

Original Effective Date: 07/21/2010

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07/01/2010	Medical Policy Committee approval
07/21/2010	Medical Policy Implementation Committee approval. New policy.
08/04/2011	Medical Policy Committee review
08/17/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/02/2012	Medical Policy Committee review
08/15/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2013	Medical Policy Committee review
09/18/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/04/2014	Medical Policy Committee review
09/17/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/08/2016	Medical Policy Committee review

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09/21/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
 09/07/2017 Medical Policy Committee review
 09/20/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 06/22/2017 Coding changes
 09/06/2018 Medical Policy Committee review
 09/19/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 Next Scheduled Review Date: 09/2019

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)[®]‡, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	S3650, S3652
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);

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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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