# Salivary Hormone Testing

**Policy #** 00259
Original Effective Date: 07/21/2010
Current Effective Date: 10/11/2021

*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.

# 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. Whembuloa 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 Sytems 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
Current Effective Date: 10/11/2021

| | |
|---|---|
| 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. |
| 09/05/2019 | Medical Policy Committee review |
| 09/11/2019 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 09/03/2020 | Medical Policy Committee review |
| 09/09/2020 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 09/02/2021 | Medical Policy Committee review |
| 09/08/2021 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |

Next Scheduled Review Date: 09/2022

# 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 2020 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);

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

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.