BlueCross BlueShield Minnesota

Blue Cross Blue Shield of Minnesota Medical Policy

Medical Policy:	VI-08-013
Topic:	Saliva Hormone Tests
Section:	Laboratory
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Saliva testing for certain hormones (e.g., estrogen, progesterone, testosterone) has been proposed for the screening, diagnosis, and monitoring of menopause and other conditions. Salivary testing has been viewed as advantageous due to its noninvasive nature and the relative ease and convenience of sample collection, which can be done in the home.

Serum is the standard specimen used for measurement of hormones. Because saliva is similar to a blood ultrafiltrate, it has been theorized that salivary hormone concentrations may correlate with free/unbound serum concentrations.

Consumers have the ability to order home salivary tests over the internet for some hormones without a physician's prescription. Results of the test may then be used to determine the need for vitamins, herbs, and phyto-hormones (e.g. phytoestrogen and phytotestosterone) to treat such conditions as infertility, menopause and aging. These may be manufactured products (e.g., vitamins, topical creams) or products compounded specifically for the individual.

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances may warrant individual consideration, based on review of applicable medical records.

Policy Position *Coverage is subject to the specific terms of the member's benefit plan.*

NOTE: Coverage may be subject to legislative mandates, including but not limited to the following, which applies prior to the policy statements:

- Minnesota Statute 62Q.473 Biomarker Testing.

The use of saliva hormone testing, such as estrogen, progesterone, testosterone, melatonin, cortisol, or dehydroepiandrosterone (DHEA), is considered **EXPERIMENTAL/INVESTIGATIVE** for **ALL** indications, including but not limited to the following, due to the lack of clinical evidence demonstrating an impact on improved health outcomes:

- Screening, diagnosis and monitoring of menopause;
- Conditions related to aging;
- Behavioral health conditions (e.g., depression, bipolar disorder, eating disorders).

Procedure Codes
S3650

Denial Statements

No additonal statements.

Links

Summary of Evidence

Use of saliva hormone testing has been proposed for a variety of indications, including conditions associated with aging in both men and women, behavioral health conditions (e.g., depression, bipolar disorder, and eating disorders), and menopause. The validity of salivary hormone test results is not known due to the lack of data correlating hormone levels in saliva to those in blood, as well as the lack of standardized collection methods, laboratory procedures, and reference values for determining the clinical significance of a given test result. In addition, there is inadequate evidence for the clinical utility of measuring salivary hormones to diagnose a condition or guide treatment. No large-scale randomized controlled trials have been published that demonstrate how knowledge of salivary hormone levels plays a meaningful role in management of a condition or improvement of health outcomes. Therefore, salivary hormone testing is considered experimental/ investigative.

Rationale

For several decades, there has been interest in testing various hormone levels using saliva as the specimen rather than blood plasma or urine. Lipid soluble hormones enter saliva by passive diffusion across the acinar cells of the salivary glands. Smaller molecules do not readily diffuse across the cells and enter between the cells through ultrafiltration. This prevents many hormones from entering saliva from serum through ultrafiltration. Measurements of salivary hormone levels are of clinical importance if they accurately reflect serum hormone levels or if a constant correlation exists between serum and salivary hormone levels.

Salivary testing has been viewed as potentially more advantageous due to its noninvasive nature and the relative ease and convenience of sample collection. However, salivary hormone tests also present several challenges, including but not limited to variance in hormone levels throughout the day (and day to day), food/drug compounds can have a transient effect, contamination by topical hormones on the hands during collection/handling, contamination by oral wounds/lesions, and inaccuracy of serum hormone levels due to conditions affecting the flow of saliva. In addition, due to contamination factors and the need to correlate hormone levels in saliva with those of serum, laboratories require expertise in performing and analyzing these tests.

A 2008 review of salivary hormone testing by Groschl identified an additional major obstacle: the lack of compliance sometimes observed in outpatient saliva donors. The author stated that no data are available to indicate whether commercial immunoassays from different manufacturers deliver equivalent results and that there is a need for standardization of both collection and analysis methods to ensure accurate results. Groschl concluded that much effort will be needed for this approach to receive acceptance over the long-term, especially by clinicians. While there are strong potential advantages to salivary testing, it cannot be considered a routine component of practice without the development of specific and standardized collection and analysis methods, analytical tools, the establishment of defined reference intervals, and implementation of independent, interlaboratory studies to verify accuracy and standardization of results.

Salivary hormones may be measured by multiple tests. Several tests have received U.S. Food and Drug Administration (FDA) 510(k) marketing clearance that use saliva samples to measure cortisol. There have been no FDA clearances for salivary testing for other hormones. In addition, many labs have developed specific tests that they must validate and perform in-house. Clinical laboratories performing salivary tests are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The laboratories use in-house reagents and methods to analyze hormone levels in saliva.

Menopause and Aging

In 2009, Flyckt et al published results for a randomized phase 3 clinical trial that compared serum and salivary testosterone levels in postmenopausal women receiving transdermal testosterone supplementation compared to those receiving a placebo. The researchers note that the gold standard for measuring biologically active testosterone (T) is serum free T by equilibrium dialysis. In this study, salivary versus serum measurements of total testosterone (TT), bioavailable testosterone (BT; consisting of free testosterone [FT] and albumin-bound testosterone), and FT from samples collected simultaneously in women who were either receiving transdermal testosterone patch supplementation (300 microg/d) or a placebo patch. Naturally and surgically post-menopausal women receiving concomitant hormone therapy were recruited to participate in a 24- to 52-week trial of a 300 microg/day transdermal testosterone patch for the treatment of hypoactive sexual desire disorder. Initial analysis demonstrated high correlations between TT, BT, and FT levels (r=0.776 to 0.855). However, there was no correlation with salivary testosterone levels for any of the serum testosterone subtypes (r=0.170 to 0.261). After log transformation, salivary testosterone correlated modestly with BT (r=0.436, p<0.001), FT (r=0.452, p<0.001), and TT (r=0.438, p<0.001). The researchers concluded that although salivary testing of testosterone concentrations is an appealing alternative because it is inexpensive and noninvasive, these findings do not support the routine use of salivary testosterone levels in postmenopausal women.

Geoffroy et al (2012) published a large cohort study assessing the relationship between cortisol levels and cognitive deficits with aging in 4,655 patients. A total of 4 salivary samples were obtained from each patient; two at 45 years: one taken 45 minutes after waking and another three hours later, and then two at 50 years using the same sampling method. The researchers reported an association between increased cortisol levels and a reduction in verbal memory and fluency tests at 50 years compared to initial scores. Although these results suggest an association between increased salivary cortisol measurements and some cognitive deficits over time, the evidence does not demonstrate that salivary hormone testing reliably improves clinical decision-making or health outcomes related to age-related cognitive function. In addition, it is unclear if the same results would have been reached if cortisol levels had been measured using some other method, such as blood sampling.

Kobori et al (2009) tested serum and saliva samples for testosterone and cortisol in 103 men aged 32-72 years who were not taking hormone medication. Questionnaires were distributed regarding sexual dysfunction and depression. Serum levels of testosterone were inversely correlated with age. In patients not taking anti-depressants, there was an inverse association between serum bioavailable cortisol/saliva cortisol and ratings of sexual dysfunction. The researchers concluded the active forms of cortisol (Bio-F and Sa-F) showed negative correlations with sexual function in men who did not take psychotropic drugs, although there was no such correlation for testosterone. Erectile dysfunction is thought to occur in patients with high levels of cortisol because of the relations between cortisol and stress. Cortisol may thus become a useful index for the evaluation of sexual function, however further studies in this field are needed.

Additional published studies have explored salivary hormone testing in menopause and conditions related to aging (Hampson et al [2016], Kerschbaum et al [2017], Rivera Gomez et al [2006], Walther et al [2016]), however, these studies do not demonstrate how the results of salivary hormone testing can be used clinically to direct patient treatment of menopause or aging.

Behavioral Health

A 2008 review published Groschl states that a wide variety of studies on stress and endocrinology have demonstrated that salivary cortisol increases dramatically under stress conditions including life-threatening situations, social isolation or economic distress, and during depression. However, these studies have not established a clinically useful relationship between cortisol levels and stress. The stress response involves the activation of the hypothalamic-pituitary-adrenal (HPA) axis and the sympathetic nervous system (SNS). This has increased interest in testing cortisol and other adrenal hormones in a variety of behavioral health and related conditions.

In 2010, Knorr et al conducted a systematic review with sequential meta-analysis and meta-regression on studies of depressed patients compared to control persons in whom salivary cortisol was measured. A total of 20 case-control studies, including 1,354 patients with depression and 1,052 control persons were identified. In a random-effects meta-analysis, salivary cortisol was increased for depressed patients as compared to control persons on average 2.58 nmol/L (95% CI: 0.95 to 4.21; p=0.002) in the morning and on average 0.27 nmol/L (95% CI: 0.03 to 0.51; p=0.03) in the evening. In a fixed effects model, the mean difference was 0.58 nmol/L (95% CI). Study sequential cumulative meta-analyses suggested random error for the difference between groups. The reviewers concluded that based on the available studies, there is not firm evidence for a difference of salivary cortisol in depressed patients and control persons and salivary cortisol is unable to discriminate between persons with and without depression.

Two neurobiological components of the stress response, cortisol and α- amylase, were analyzed in a small study aimed at understanding the role of stress response in the pathophysiology of eating disorders. Monteleone et al (2011) assessed salivary cortisol and α-amylase responses to the Trier Social Stress Test (TSST) in symptomatic patients with anorexia nervosa (n=7) and bulimia nervosa (n=8) compared to age-matched healthy females (n=8). Patients underwent the TSST between 1530 and 1700 hours. Salivary cortisol and α- amylase levels were measured by an enzyme-linked immunosorbent assay (ELISA). Compared to healthy women, anorexia nervosa patients showed a normal cortisol response to the TSST, although this occurred at significantly increased hormone levels, and an almost complete absence of response of α- amylase. Women with bulimia nervosa, however, exhibited enhanced pre-stress levels of salivary α-amylase but a normal response of the enzyme and cortisol to the TSST. The researchers concluded that these findings demonstrated, for the first time, the occurrence of an asymmetry between the HPA axis and SNS components of the stress response in the acute phase of anorexia nervosa but not in bulimia nervosa, however these results should be regarded as preliminary. Moreover, they stated that pathophysiological significance of this asymmetry remains to be determined.

Kamali et al (2012) published results for a study that compared HPA axis activity in bipolar individuals with and without suicidal behavior and unaffected healthy controls through measurement of salivary cortisol. Salivary cortisol was collected for 3 consecutive days in 29 controls, 80 bipolar individuals without a history of suicide, and 56 bipolar individuals with a history of suicide. Clinical factors that affect salivary cortisol were also examined. A history of suicide was associated with a 7.4% higher bedtime salivary cortisol level in bipolar individuals. There was no statistical difference between non-suicidal bipolar individuals and controls in bedtime salivary cortisol, and awakening salivary cortisol was not different between the 3 groups. The researchers concluded that bipolar individuals with a past history of suicidal behavior exhibit hyperactivity in the HPA axis. This biological marker remains significant regardless of demographic factors, mood state, severity and course of illness. This finding in bipolar disorder is consistent with the evidence for altered HPA axis functioning in suicide and mood disorders and is associated with a clinical subgroup of bipolar patients at elevated risk for suicide based on their history, and in need of further attention and study. The limitations of this study included measurement of salivary cortisol as a home-based collection by the study subjects, and the retrospective clinical data which was primarily based on historical accounts rather than real-time assessment.

Technology Assessments

Hayes evaluates a wide range of medical technologies and provides evidence-based assessments to determine impacts on patient safety and health outcomes. The Hayes Rating has become the industry's benchmark and reflects the strength and direction of the evidence regarding a medical technology. The Hayes Rating is D2 for salivary hormone testing in postmenopausal women for determination of menopausal state or for guidance of treatment decisions. This Rating reflects the insufficient published evidence to assess the safety and/or impact on health outcomes and the very low quality of the available evidence.

Practice Guidelines & Position Statements

In 2012, the American College of Obstetricians and Gynecologists (ACOG) Committee on Gynecologic Practice and the American Society for Reproductive Medicine (ASRM) Practice Committee published a committee opinion on the use of bioidentical hormone therapy as a treatment for menopause. The joint committee concluded that evidence is inadequate to support increased efficacy or safety for individualized hormone therapy regimens based on salivary, serum, or urinary testing. The committee stated that there is no evidence that hormonal levels in saliva are biologically meaningful. In addition, whereas saliva is an ultrafiltrate of the blood and in theory should be amenable to testing for “free” (unbound) concentrations of hormones, salivary testing does not currently offer an accurate or precise method of hormone testing. They elaborate on several problems with salivary testing and monitoring of free hormone levels: “First, salivary levels do not consistently provide a reasonable representation of endogenous, circulating serum hormones. There is large within-patient variability in salivary hormone concentrations, especially when exogenously administered hormones are given. Salivary hormone levels vary depending on diet, time of testing, and the specific hormone being tested. Second, because the pharmacokinetics of exogenously administered compounded hormones cannot be known, it is not possible to estimate with reliability how and when to test saliva to obtain a representative result. Third, saliva contains far lower concentrations of hormone than serum and is prone to contamination with blood, infectious agents, and epithelial cells – all of which may affect the level of hormone to be measured.”

In 2023, ACOG published a clinical consensus that reaffirmed the 2012 committee opinion. The authors concluded that data on the interpretation of adjunct hormone tests for prescribing and dosing compounded bioidentical menopausal hormone therapy are limited; thus, these tests are not recommended for these indications. There are many claims regarding the utility of individualizing hormone therapy based on testing of saliva, serum, or blood. However, individualized testing is useful only when there is a narrow therapeutic window for a drug or class of drugs and the serum hormone levels can be reliably assessed, and if the results would change management. Although proponents claim that salivary testing can help tailor hormone therapy, salivary testing does not offer accurate or precise assessment of hormone levels.

In 2022, the North American Menopause Society (NAMS) published an updated position statement regarding hormone therapy. According to the statement, “salivary and urine hormone testing to determine dosing are unreliable and not recommended.” The position statement elaborates that compounded bioidentical hormone therapy has been prescribed or dosed on the basis of serum, salivary, or urine hormone testing; however, the use of such testing to guide hormone therapy dosing is considered unreliable because of differences in hormone pharmacokinetics and absorption, diurnal variation, and interindividual and intraindividual variability.

In 2017, the American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) published an updated position statement on menopause. The statement recommends against the use of salivary tests for sex hormone concentrations and noted large intra-subject variability.

The AACE also published a medical guideline for clinical practice in 2011 for the diagnosis and treatment of menopause. The guideline notes that large intrasubject variability in salivary sex hormone concentrations has been reported and recommends against the use of salivary tests for sex hormone concentrations. The guideline also indicates that despite the lack of approval by either the FDA or CLIA, “salivary hormone level testing is recommended by many bio-identical hormone proponents as a means of providing patients with ‘individualized’ therapy.”

Minnesota Mandate

Minn. Stats. §62Q.473 Biomarker Testing, effective January 1, 2025, applies to health plans offered, issued, or renewed on or after the effective date. Minn. Stat. §62Q.473, subd. 1 and 2 state the following:

Subd. 1. Definitions.

(a) For the purposes of this section, the terms defined in this subdivision have the meanings given.

(b) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention, including but not limited to known gene-drug interactions for medications being considered for use or already being administered. Biomarkers include but are not limited to gene mutations, characteristics of genes, or protein expression.

(c) "Biomarker testing" means the analysis of an individual's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to single-analyst tests; multiplex panel tests; protein expression; and whole exome, whole genome, and whole transcriptome sequencing.

(d) "Clinical utility" means a test provides information that is used to formulate a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision. The most appropriate test may include information that is actionable and some information that cannot be immediately used to formulate a clinical decision.

(e) "Consensus statement" means a statement that:

(1) describes optimal clinical care outcomes, based on the best available evidence, for a specific clinical circumstance; and

(2) is developed by an independent, multidisciplinary panel of experts that:

(i) uses a rigorous and validated development process that includes a transparent methodology and reporting structure; and

(ii) strictly adheres to the panel's conflict of interest policy.

(f) "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline that:

(1) establishes a standard of care informed by

(i) a systematic review of evidence, and

(ii) an assessment of the risks and benefits of alternative care options; and

(2) is developed by an independent organization or medical professional society that:

(i) uses a transparent methodology and reporting structure; and

(ii) adheres to a conflict of interest policy. Nationally recognized clinical practice guideline includes recommendations to optimize patient care.

Subd. 2. Biomarker testing; coverage required.

(a) A health plan must provide coverage for biomarker testing to diagnose, treat, manage, and monitor illness or disease if the test provides clinical utility. For purposes of this section, a test's clinical utility may be demonstrated by medical and scientific evidence, including but not limited to:

(1) nationally recognized clinical practice guidelines as defined in this section;

(2) consensus statements as defined in this section;

(3) labeled indications for a United States Food and Drug Administration (FDA) approved or FDA-cleared test, indicated tests for an FDA-approved drug, or adherence to warnings and precautions on FDA-approved drug labels; or

(4) Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations.

(b) Coverage under this section must be provided in a manner that limits disruption of care, including the need for multiple biopsies or biospecimen samples.

(c) Nothing in this section prohibits a health plan company from requiring a prior authorization or imposing other utilization controls when approving coverage for biomarker testing.

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