Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/25**
(See policy history boxes for previous effective dates)

Title: Salivary Testing for Hormone Levels

Description/Background

The diagnosis of Cushing's syndrome (CS) is often a challenge. Although common in the general population, features such as weight gain, depression, hypertension, and menstrual irregularities, may raise the possibility of Cushing's syndrome. The conditions associated with Cushing's syndrome (such as obesity, hypertension, and diabetes) are commonly encountered in clinical practice. Patients with Cushing's syndrome have been identified by using screening tests such as abnormal low-dose dexamethasone suppression test, elevated urine free cortisol (UFC), an absence of diurnal rhythm of plasma cortisol, or an elevated late-night plasma cortisol. Up to 30% of urine cortisol and dexamethasone suppression screening tests may return an incorrect result, suggesting that better tests are needed. Because the concentration of cortisol in the saliva is in equilibrium with the free (active) cortisol in the plasma, measurement of salivary cortisol in the evening (nadir) and morning (peak) may be a simple and convenient screening test for Cushing's syndrome. The salivary cortisol concentration is an indicator of the plasma free cortisol concentration. They circumvent the physiological, pathological, and pharmacological changes due to corticosteroid-binding globulin alterations and offer a practical approach to assess pituitary-adrenal function. Salivary cortisol measurements are an index of plasma free cortisol concentrations.[1]

Salivary tests of various hormones include, but are not limited to estrogen, estradiol, estriol, estrone, progesterone, testosterone, melatonin and dehydroepiandrosterone (DHEA). The tests are noninvasive, may be obtained without a prescription, and are marketed to consumers for home-based testing by pharmacies, laboratories, and through internet sites. The salivary hormone tests have been proposed as a method for screening, diagnosis or monitoring of menopause, preterm labor, and other conditions.

Regulatory Status

Laboratory tests are regulated under the Clinical Laboratory Improvement Act (CLIA). There are some salivary test kits available via mail order or the Internet that are cleared for marketing by the U.S. Food and Drug Administration.

Medical Policy Statement

Individuals with signs and symptoms of Cushing's syndrome, late night salivary cortisol testing is **established**.

Any testing of salivary hormone testing of estrogens, progesterone, testosterone, melatonin or DHEA is considered **experimental/investigational.** Testing has not been shown to improve clinical health outcomes.

Inclusionary and Exclusionary Guidelines

Inclusions:

- Individuals with signs and symptoms of Cushing's syndrome, late night salivary cortisol testing is **established**.

Exclusions:

Any testing of salivary hormones: estrogens, progesterone, testosterone, melatonin, and DHEA is considered experimental and investigational for the screening, diagnosis, **and/or** monitoring of **ANY** of the following conditions:

- Ovulation
- Menopause
- Changes related to aging
- Preterm labor
- Other gonadal dysfunction such as:
    - Infertility
    - Endometriosis
    - Polycystic ovary disease (PCOS)
    - Premenstrual syndrome
    - Osteoporosis
    - Sexual dysfunction
    - Seasonal affective disorder
    - Depression
    - Multiple sclerosis
    - Sleep disorders
    - Diseases related to aging

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

82530	82533

Other codes (investigational, not medically necessary, etc.):

82626	82627	82670	82671	82672	82677
82679	82681	84144	84402	84403	84410
S3650	S3652				

Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Clinical signs and symptoms, such as weight gain, depression, hypertension, and menstrual irregularities, although common in the general population, may raise the possibility of Cushing's syndrome. Up to 30% of urine cortisol and dexamethasone suppression screening tests may return an incorrect result, suggesting that better tests are needed. According to Papanicolaou et al.[2] this study evaluated the utility of nighttime salivary cortisol measurement as a screening test for Cushing's syndrome. The study involved 139 inpatients and 4 outpatients with possible Cushing's syndrome, 16 inpatients and 7 outpatients with other nonadrenal disorders, and 34 healthy outpatients. Using cut points that excluded all subjects without Cushing's syndrome, they were compared to the sensitivity for the detection of Cushing's syndrome of nighttime salivary cortisol levels (2330 and 2400 h for inpatients and bedtime for outpatients), simultaneous inpatient serum cortisol levels, and urine glucocorticoid excretion. An assay- specific inpatient 2400-h salivary cortisol or an outpatient bedtime salivary cortisol greater than 550 ng/dl (15.2 nmol/liter) identified 93% of patients with Cushing's syndrome (confidence interval, 89-98%) and excluded all individuals without the disorder. Salivary cortisol measurements worked as well as plasma measurements and better than urine glucocorticoid excretion. Bedtime salivary cortisol measurement is a practical and accurate screening test for the diagnosis of Cushing's syndrome.

The conditions associated with Cushing's syndrome (such as obesity, hypertension, and diabetes) are commonly encountered in clinical practice. Patients with Cushing's syndrome have been identified by an abnormal low-dose dexamethasone suppression test, elevated urine free cortisol (UFC), an absence of diurnal rhythm of plasma cortisol, or an elevated late-night plasma cortisol. Because the concentration of cortisol in the saliva is in equilibrium with the free (active) cortisol in the plasma, measurement of salivary cortisol in the evening (nadir) and morning (peak) may be a simple and convenient screening test for Cushing's syndrome. The purpose of this study was to evaluate the usefulness of the measurement of late-night and morning salivary cortisol in the diagnosis of Cushing's syndrome. In the Raff study et al,1998,[3] there were 73 healthy subjects, and 78 patients referred for the diagnosis of Cushing's

syndrome. Salivary cortisol was measured at 2300 h and 0700 h using a simple, commercially available saliva collection device and a modification of a standard cortisol RIA. In addition, 24-h UFC was measured within 1 month of saliva sampling. Patients with proven Cushing's syndrome (N = 39) had significantly elevated 2300-h salivary cortisol (24.0 +/- 4.5 nmol/L), as compared with normal subjects (1.2 +/- 0.1 nmol/L) or with patients referred with the clinical features of hypercortisolism in whom the diagnosis was excluded or not firmly established (1.6 +/- 0.2 nmol/L; N = 39). Three of 39 patients with proven Cushing's had 2300-h salivary cortisol less than the calculated upper limit of the reference range (3.6 nmol/L), yielding a sensitivity of 92%; one of these 3 patients had intermittent hypercortisolism, and one had an abnormal diurnal rhythm (salivary cortisol 0700-h to 2300-h ratio<2). An elevated 2300-h salivary cortisol and/or an elevated UFC identified all 39 patients with proven Cushing's syndrome (100% sensitivity). Salivary cortisol measured at 0700 h demonstrated significant overlap between groups, even though it was significantly elevated in patients with proven Cushing's syndrome (23.0 +/- 4.2 nmol/L), as compared with normal subjects (14.5 +/- 0.8 nmol/L) or with patients in whom Cushing's was excluded or not firmly established (15.3 +/- 1.5 nmol/L). Late-night salivary cortisol measurement is a simple and reliable screening test for spontaneous Cushing's syndrome. In addition, late-night salivary cortisol measurements may simplify the evaluation of suspected intermittent hypercortisolism, and they may facilitate the screening of large high-risk populations (e.g., patients with diabetes mellitus).

One of the primary hormones that diffuses freely into saliva and can be well-approximated by salivary measurements is cortisol. Cortisol is a steroid hormone that is produced due to stress. Salivary flow rate does not affect cortisol concentration, and salivary cortisol correlates well with serum-free cortisol. This property can be used to identify adrenal insufficiencies and other related disorders (Nieman, 2019).[4] For example, the presence of Cushing syndrome (CS) is suggested by signs of hypercortisolism, such as proximal myopathy, facial plethora, and wide purplish striae. However, none of these are pathognomonic, and many are nonspecific (such as obesity or hypertension). As a result, the diagnosis must be confirmed by biochemical tests, one of which is a salivary cortisol measurement (Nieman, 2022b).[5] Fleseriu et al. [6] reviewed the recurrence of hypercortisolemia after an initial treatment for CS seems to be predicted earlier by late night salivary cortisol (LNSC) testing compared to urinary free cortisol excretion.

According to (Putignano, et al.2003)[7] , the determination of late-night salivary cortisol levels has been reported to be a sensitive and convenient screening test for CS. However, no studies have included a comparison with other screening tests in a setting more closely resembling clinical practice, i.e., few patients with CS to be distinguished from patients with pseudo-Cushing states (PC), including the large population of obese patients. The aim of this study was to compare the diagnostic performance of midnight salivary cortisol (MSC) measurement with that of midnight serum cortisol (MNC) and urinary free cortisol (UFC) in differentiating 41 patients with CS from 33 with PC, 199 with simple obesity, and 27 healthy normal weight volunteers. Three patients with CS had MSC levels lower than the cut-off point derived from receiver operator characteristic analysis (9.7 nmol/liter), yielding a sensitivity for this parameter of 92.7%. In the whole study population, no statistically significant differences in terms of sensitivity, specificity, diagnostic accuracy, and predictive values were observed among tests. In particular, the overall diagnostic accuracy for MSC (93%; 95% confidence interval, 90.1-95.9%) was similar to those of UFC (95.3%; 94.1-96.5%) and MNC (95.7%; 93.4-98%; both P = NS). The diagnostic performance of MSC was superimposable to that of MNC also within the area of overlap in UFC values (<or =569 nmol/24 h) between CS and PC. In conclusion, MSC measurement can be recommended as a first-line test for CS in both low risk (simple obesity)

and high-risk (i.e., PC) patients. Given its convenience, this procedure can be added to tests traditionally used for this purpose, such as UFC and MNC.

Zerikly et al.[8] examined the diagnostic effectiveness of late-night salivary cortisol (LNSC) in detecting Cushing's syndrome. Using liquid chromatography-tandem mass spectrometry (LC-MS/MS), the study found that LNSC measurement is reliable and non-invasive screening tool for hypercortisolism. The results indicate that LNSC has high sensitivity and specificity, making it an effective method for identifying patients with suspected Cushing's syndrome. This approach offers advantages over traditional blood tests due to its convenience and accuracy.

According to Genova Diagnostics et al.[9], there are few indications for the measurement of hormone levels to evaluate success of therapy when treating a postmenopausal [individual] with hormones. If treatment is initiated for symptom control, therapy should be titrated to the alleviation of symptoms, not a laboratory value (ACOG & ASRM, 2012). A salivary hormone test has been developed by Genova Diagnostics, which evaluates levels of hormones in [individuals] during perimenopause, menopause, and postmenopause.

Salivary testing is used to tailor hormone therapy, but it does not offer accurate or precise assessment of hormone levels. Steroid hormones mostly are bound to albumin, with less than 5% circulating in free form. Estrogen levels are extremely low in saliva which makes it difficult methodologically for measurement. Progesterone is present in the saliva at higher levels but circulating serum levels do not necessarily reflect the amount of progesterone in the tissues. Currently, there are no FDA-approved salivary or urinary tests for measuring steroid hormones as reviewed by the American College of Obstetrics and Gynecology in their 2023 guidelines[10] regarding compounded bioidentical menopausal hormones.

A study by Lewis et al. (2002)[11] focusing on salivary progesterone measurements found major variation when a progesterone cream was applied to several post-menopausal individuals. Salivary measurements were collected at zero, one, three, four, seven, and eight weeks. The average baseline for the 20 mg/g cream group was found to be 0.25 ± 0.12 nmol/L, but the measurement at one week was 82.11 ± 104.52 nmol/L; similar enormous variations were found at three and seven weeks, as well as the 40 mg/gm cream group. In contrast, the placebo group's baseline was 0.43±0.21 and 0.38±0.20 in week eight. Sakkas et al.[12] summarized a finding with inconsistent salivary progesterone levels was even found among premenopausal individuals obtaining in vitro fertilization (IVF); on the other hand, salivary estradiol was found to be correlative to serum-based assessment, and could be a less invasive alternative to blood draws for ovarian stimulation during IVF cycles.

Summary of Evidence

Serum levels are the standard for some hormone measurement. However, in Cushing's syndrome, there are several studies that highlight the diagnostic accuracy of late-night salivary cortisol (LNSC), with high sensitivity and specificity. The sensitivity improved (100%) in response to the combination of 2300 h and overnight 1-mg DEX salivary cortisol suppression tests to differentiate between obese and CS subjects.

Our data indicate that nighttime sample and overnight 1-mg DEX suppression salivary cortisol tests are sensitive markers for the diagnosis of CS. In addition, the combination of the two tests improves the ability to differentiate between obese and CS patients and may be useful for out-patient screening. There is sufficient evidence that bedtime salivary cortisol measurement

is a practical and accurate screening test for the diagnosis of Cushing's syndrome Late night salivary testing has been shown to improve clinical health outcomes.

Hormone concentrations using saliva may vary and not provide an accurate clinical assessment in all other conditions. Due to their variability, salivary hormone measurements are unreliable. There is insufficient evidence for the use of salivary hormone testing of estrogens, progesterone, testosterone, melatonin, or DHEA. Salivary hormone testing is not appropriate for evaluating, diagnosing, or monitoring conditions such as ovulation, menopause, changes related to aging, preterm labor, or another gonadal dysfunction. There was insufficient evidence to show that this testing improved clinical health outcomes.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

In the 2011 American Association of Clinical Endocrinologists' Medical Guidelines for Clinical Practice for the Diagnosis and Treatment of Menopause, salivary hormone concentrations were addressed. The guidelines noted that studies have revealed large intrasubject variability in salivary sex hormone concentrations. The fluctuations are dependent on numerous variables, including diet, hydration, and circadian rhythm – and that these conditions are difficult to standardize.[13]

In 2012, The North American Menopause Society (NAMS) published a position statement on hormone therapy[14] that stated salivary hormone testing has been proven to be inaccurate and unreliable. The position statement was updated in 2017[15] and continues to affirm: that "…salivary testing for hormone therapy is considered unreliable because of differences in hormone pharmacokinetics and absorption, diurnal variation, and interindividual and intraindividual variability."

In 2012, and reaffirmed in 2020, the American College of Obstetricians and Gynecologists (ACOG)[16] noted:

> "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. There are 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."

Finally, the guideline wrote 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 ” (ACOG & ASRM, 2012). This guideline was reaffirmed in 2020.

The most recent ACOG practice bulletin on Prediction and Prevention of Spontaneous Preterm Birth (August 2021)[17] states that there are a variety of tests and monitoring modalities that have been proposed as markers for preterm delivery risk, including salivary hormone concentrations. “…These emerging prediction methods should be considered investigational, and routine adoption into clinical practice is not recommended.”

The ACOG and ASRM published a clinical consensus stating that “although proponents claim that salivary testing can help tailor hormone therapy, salivary testing does not offer accurate or precise assessment of hormone levels. Steroid hormones mostly are bound to albumin, with less than five percent circulating in free form. Estrogen levels are extremely low in saliva, which make it methodologically challenging to measure. Progesterone is present in the saliva at higher levels, but circulating levels do not necessarily reflect the levels present in the tissue.” Currently, there are no FDA-approved salivary or urinary tests for steroid hormone measurement (ACOG, 2023).[10]

Government Regulations
National/Local:

There is no national or local coverage determination.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 8/26/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/27/05	7/27/05	7/26/05	Joint policy established
7/1/08	7/3/08	7/3/08	Routine maintenance
7/1/10	4/20/10	4/20/10	Routine maintenance
1/1/13	10/16/12	10/16/12	Routine maintenance, title changed from Salivary Testing for Hormonal Levels to Salivary Testing for Hormone Levels
7/1/15	4/24/15	5/8/15	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
3/1/17	12/13/16	12/13/16	Routine maintenance
3/1/18	12/12/17	12/12/17	Routine maintenance Updated references
3/1/19	12/11/18		Routine maintenance
3/1/20	12/17/19		Routine maintenance
3/1/21	12/15/20		Routine maintenance
3/1/22	12/14/21		Routine maintenance Ref 5 added
3/1/23	12/20/22		Routine maintenance (jf) Vendor: Avalon
1/1/24	10/17/23		Routine maintenance (jf) Vendor managed: Avalon
1/1/25	10/15/24		Routine maintenance (jf) Vendor managed: Avalon G2120 Salivary Hormone Testing Added Ref: 1-12 Edits to the description, rationale, summary of evidence, MPS, inclusionary and exclusionary criteria -Addition of the following codes as EST: 82530 and 82533 -Addition of the following codes as E/I: 82626, 82627,82670,82671,82672,82677, 82679,82681,84144,84402,84403, and 84410

			-Change policy from E/I to Mixed status

Next Review Date: 4th Qtr., 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SALIVARY TESTING FOR HORMONE LEVELS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.