

Salivary Hormone Testing

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Dates Reviewed: 08/2006, 12/2006, 12/2007, 01/2009, 02/2011, 03/2012, 01/2013, 12/2013, 08/2015, 08/2016, 08/2017, 04/2019, 04/2020

Developed By: Medical Necessity Criteria Committee

I. Description

Over the last several years, there has been an increased interest in testing hormone levels using saliva rather than blood, plasma, or urine. The tests available include but are not limited to progesterone, estrogen, testosterone, melatonin, and dehydroepiandrosterone (DHEA). The advantages to salivary hormone testing include the noninvasive nature and ease and convenience of sample collection, which can be done in the home. Salivary hormone tests are primarily promoted for the evaluation of menopause and aging and are now available to consumers over the internet without the need of a physician's prescription.

Cortisol salivary hormone testing can be utilized to diagnose Cushing's syndrome. Cushing's syndrome is a hormonal disorder caused by prolonged exposure of the body's tissues to high levels of cortisol hormone. While other conditions can have the same symptoms and signs, Cushing's syndrome can be diagnosed by measuring excessive cortisol levels. Cortisol levels vary throughout the day but drop considerably during the night. Due to the limitations of the current available diagnostic tests for Cushing's syndrome (dexamethasone suppression test and 24-hour free cortisol level test) late night salivary cortisol test is a simple way to screen for Cushing's syndrome. This test has a high diagnostic specificity and sensitivity.

II. Criteria: CWQI HCS-0060

- A. Salivary hormone testing is medically necessary if **ALL** of the following criteria are met:
- The test is requested to evaluate for suspected hypercortisolism of Cushing's syndrome in children and adults.
 - The test is being ordered by a qualified health professional; and
 - The test is performed in a CLIA (Clinical Laboratory Improvement Amendments) approved laboratory.
 - The test is **NOT** being requested for **ALL** of the following:
 - Diagnosis and/or monitoring of menopause
 - Diagnosis and/or monitoring of diseases related to aging (i.e. osteoporosis)
 - Any other indication not mentioned above.

III. Information Submitted with the Prior Authorization Request:

1. Chart notes indicating suspicion of hypercortisolism

IV. CPT or HCPC codes covered:

Codes	Description
82530	Cortisol; free [other than late night salivary cortisol for diagnosing Cushing's syndrome]
82533	total [other than late night salivary cortisol for diagnosing Cushing's syndrome]

V. CPT or HCPC codes NOT covered:

Codes	Description
82626	Dehydroepiandrosterone (DHEA)
82627	Dehydroepiandrosterone-sulfate (DHEA-S)
82670	Estradiol
82671	Estrogens; fractionated
82672	total
82677	Estriol
82679	Estrone
83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method [salivary testing for anti-tissue transglutaminase for the diagnosis of celiac disease]
83520	quantitative, not otherwise specified [not covered for measurement of salivary level of interleukin-8 as biomarkers for oral pre-cancer and oral squamous cell carcinoma] [not covered for salivary antibody testing (IgA, IgG, IgM) for the diagnosis of Sicca syndrome]
84144	Progesterone
84402	Testosterone; free
84403	total
84436	Thyroxine; total
84437	requiring elution (eg, neonatal)
84439	free
84443	Thyroid stimulating hormone (TSH)
84479	Thyroid hormone (T3 or T4) uptake or thyroid hormone binding ratio (THBR)
84480	Triiodothyronine T3; total (TT-3)
84481	free
86316	Immunoassay for tumor antigen, other antigen, quantitative (eg, CA 50, 72-4, 549), each [not covered for measurement of salivary level of CYFRA 21-1 as biomarkers for oral pre-cancer and oral squamous cell carcinoma]
88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)

88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure
88344	Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody stain procedure
S3650	Saliva test, hormone level; during menopause

VI. Annual Review History

Review Date	Revisions	Effective Date
01/2013	Annual Review: Added table with review date, revisions, and effective date.	01/23/2013
12/2013	Annual Review: No changes	12/19/2013
08/2015	Annual Review- added CPT/HCPC, ICD-9 and ICD-10 codes	08/26/2015
08/2016	Annual Review – no change to criteria, deleted ICD9 codes	08/31/2016
08/2017		08/23/2017
04/2019	Annual Review – no changes	05/01/2019
04/2020	Annual Review: No changes	05/01/2020

VII. References

1. American Association of Clinical Endocrinologists (AACE). Medical guidelines for clinical practice for management of menopause. *Endocrine Practice*. 1999; 5:355-366.
2. Carroll T, Raff H, Findling JW. Late-night salivary cortisol measurement in the diagnosis of Cushing's syndrome. *Nat Clin Pract Endocrinol Metab*. 2008;4(6):344-350.
3. Lawrence HP. Salivary markers of systemic disease: noninvasive diagnosis of disease and monitoring of general health. *J Can Dent Assoc*. 2002;68(3):170-4.
4. Nieman LK, Biller BM, Findling JW, Newell-Price J, Savage MO, Stewart PM, Montori VM. The diagnosis of Cushing's syndrome: An Endocrine Society Practice Guideline. *J Clin Endocrinol Metab*. Accessed on March 24, 2012 at: <http://jcem.endojournals.org/cgi/content/full/93/5/1526?maxtoshow=&hits=10&RESULTFORMAT=&author1=Nieman+&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT>
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6. Raff H. Utility of salivary cortisol measurements in Cushing's syndrome and adrenal insufficiency. *J Clin Endocrinol Metab*. 2009;94(10):3647-3655.
7. Rubin GJ, Hotopf M, Papadopoulos A, Cleare A. Salivary cortisol as a predictor of postoperative fatigue. *Psychosom Med*. 2005;67(3):441-447
8. Vining RF, McGinley RA. The measurement of hormones in saliva: possibilities and pitfalls. *J Steroid Biochem*. 1987;27(1-3):81-94.
9. Physician Advisors

Appendix 1 – Applicable Diagnosis Codes:

Codes	Description
E24.0	Pituitary-dependent Cushing's disease
E24.2	Drug-induced Cushing's syndrome
E24.3	Ectopic ACTH syndrome
E24.8	Other Cushing's syndrome
E24.9	Cushing's syndrome, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC