

Policy terminated because Medicaid covered services are covered in the same manner as Health Choice.

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1.0 Description of the Procedure, Product, or Service

Many products of physiology and metabolism are known to be excreted by the body into the saliva. It has been proposed that measurement of these substances may be useful in some cases as an indicator of some disease states. For many substances the concentrations available in saliva do not correlate well with various disease states, are not as accurate as other testing methods, or have yet to be established as useful tools in the management or detection of disease. The tests are non-invasive and in some instances, may be obtained without a prescription. Most test kits are marketed to consumers as a tool for personal wellness and surveillance by pharmacies or labs, through the Internet or mail order services. Salivary hormone tests include Estrogens, Progesterone, Testosterone, Cortisol, Melatonin and Dehydroepiandrosterone (DHEA).

1.1 Medical Term Definitions

- a. Cortisol: the major natural glucocorticoid elaborated by the adrenal cortex; it affects the metabolism of glucose, protein, and fats and has mineralocorticoid activity.
- b. Endogenous: developing or originating within the organism or arising from causes from within the organism.
- c. Hormone: a chemical substance produced in the body by an organ, cells of an organ, or scattered cells, having a specific regulatory effect on the activity of an organ or organs.
- d. Hypercortisolism: a genetic or acquired condition resulting in elevated levels of glucocorticoids, often as a result of tumors in adrenal or pituitary glands. Leads to significant weight gain, particularly on the back (causing a “buffalo hump”) and face. More commonly caused by steroid use/abuse, in which case it is called Cushing syndrome medicamentosus.
- e. Menopause: cessation of menstruation in the human female, occurring usually around the age of 50.
- f. Salivary: pertaining to the saliva.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

Note: Most children will be able to get all the services they need under the core (basic) plan of NC Health Choice. A child who qualifies as having special needs may be able to receive additional services not covered by the core plan.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Salivary hormone testing for cortisol is covered under the NC Health Choice Program when it is determined to be medically necessary because the following medical criteria are met:

Salivary hormone testing by radioimmunoassay for cortisol is considered medically necessary when performed to evaluate suspected endogenous hypercortisolism of Cushing's syndrome (CS) in recipients. The testing should be ordered by a physician. Refer to **Section 6.0** regarding laboratory accreditation.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

- a. Salivary testing of cortisol is not covered for any indication other than as specified in **Subsection 3.2**. Salivary cortisol testing for screening, diagnosing, or monitoring any other health condition, or any other indication, is considered investigational. The NC Health Choice Program does not cover investigational services.
- b. Salivary hormone testing of estrogen, progesterone, testosterone, melatonin, or dehydroepiandrosterone (DHEA) for the screening, diagnosis, or monitoring of menopause (pre, peri, and post), aging, hormone replacement therapy, or any other indication is considered investigational. The NC Health Choice Program does not cover investigational services.

4.3 Policy Guidelines

An assessment by the Institute for Clinical Systems Improvement (2008) concluded: "Currently, there is insufficient evidence in the published scientific literature to permit conclusions concerning the use of salivary hormone testing for the diagnosis, treatment or monitoring of menopause and aging."

The American College of Obstetricians and Gynecologists (ACOG), in their Committee Opinion #322, Compounded Bioidentical Hormones, address salivary hormone level testing as not meaningful because salivary hormone levels vary within each woman depending on her diet, the time of day, the specific hormone being tested, and other variables (ACOG 2005).

The North American Menopause Society (NAMS) in their position statement has concluded that "Salivary testing is not considered to be a reliable measure of testosterone levels."

A National Institutes of Health State-of-the-Science Conference Statement on Management of Menopause-related Symptoms (2005) reached the following conclusions about salivary hormone testing and bioidentical hormones: "Bioidentical hormones, often called "natural" hormones, are treatments with individually compounded recipes of a variety of steroids in various dosage forms, with the composition and dosages based on a person's salivary hormone concentration. These steroids may include estrone, estradiol, estriol, DHEA, progesterone, pregnenolone, and testosterone. There is a paucity of data on the benefits and adverse effects of these compounds."

Cushing's syndrome can be difficult to diagnose and is often a challenge for clinicians because other conditions share the same signs and symptoms. The laboratory investigations of CS are based on the demonstration of excessive cortisol secretion. Cortisol levels normally rise and fall throughout the day. In recipients without CS, the levels drop significantly overnight. Several tests have been used extensively, but each of the currently available biochemical tests for the diagnosis of CS has limitations (24-hour urine free Cortisol level and low dose dexamethasone suppression test). Late night salivary cortisol test is a simple way to screen for CS and it has been found to have high diagnostic sensitivity and specificity. Major advantages of this method are the reliability, non-invasiveness, and use in ambulatory recipients.

Although saliva testing kits to evaluate hormone levels during menopause are currently available, these kits are not subject to FDA Approval. Several testing methods for salivary cortisol have been cleared for marketing by the FDA.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for salivary hormone testing.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- meet NCHC qualifications for participation;

- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Note: The U.S. Food and Drug Administration (FDA) regulates laboratory tests under the Clinical Laboratory Improvement Act (CLIA). The CLIA stipulates that clinical laboratories need to be accredited by the College of American Pathologists Laboratory Accreditation Program. Salivary hormone testing by radioimmunoassay for cortisol to evaluate suspected endogenous hypercortisolism of Cushing's syndrome (CS) must be performed in a CLIA-approved laboratory

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
February 29, 2012	Throughout	Policy Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Codes	
82530	82533

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Office and Home

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.