Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP162

Section: Medical Benefit Policy

Subject: Salivary Hormone Testing for Menopause and Aging

Applicable line of business:

Commercial	**x**	**Medicaid**	**x**
Medicare	**x**	**ACA**	**x**
CHIP	**x**		

I. Policy: Salivary Hormone Testing for Menopause and Aging

II. Purpose/Objective:

To provide a policy of coverage regarding Salivary Hormone Testing for Menopause and Aging

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:
Saliva can be analyzed for lipid-soluble hormones such as estrogen, testosterone, progesterone, melatonin, cortisol and DHEA (Dehydroepiandrosterone). Salivary hormone levels reflect the free, unbound and active, hormone concentration. Measurements of the salivary concentrations are of clinical significance only when they accurately reflect serum hormone levels. Saliva testing is viewed as a potentially more advantageous method of testing due to its non-invasive nature and ease of convenience of sample collection, which can be done at home. Because of the fluctuation in hormone levels and ease of sampling, saliva sampling can be used to produce a menopausal hormone profile and is alleged to be helpful in monitoring hormone replacement therapy.

EXCLUSIONS:
The Plan does **NOT** provide coverage for the use of saliva testing for the screening, diagnosis and/or monitoring of menopause and aging because it is considered **experimental, investigational or unproven.** The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment.**

CODING ASSOCIATED WITH: Saliva Hormone Testing for Menopause and Aging
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

S3650	Saliva test, Hormone level: during menopause
D0418	Analysis of saliva sample – Chemical or biological analysis of saliva sample for diagnostic purposes

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
Geisinger Technology Assessment Committee Triage Group.Salivary testing for Menopause. Sept. 29, 2005.

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Navarro MA, Alia P, Ruiz R, Valles A, Orozco P. Relationship between blood levels of sex hormones binding globulin, testosterone levels in blood and saliva and body morphology in premenopausal women. Med Clin (Barc) 1996 Mar 23;106(11):405-8.

Shirtcliff EA, Granger DA, Schwartz EB, Curran MJ, Booth A, Overman WH. Assessing estradiol in biobehavioral studies using saliva and blood spots: simple radioimmunoassay protocols, reliability, and comparative validity. Horm Behav. 2000 Sep; 38(2):137-47.

Tivis LJ, Richardson MD, Peddi E, Arjmandi B. Saliva versus serum estradiol: implications for research studies using postmenopausal women. Prog Neuropsychopharmacol Biol Psychiatry. 2005 June; 29(5): 727-32.

Kivlighan KT, Granger DA, Schwartz EB. Blood contamination and the measurement of salivary progesterone and estradiol. Horm Behav. 2005 March; 47(3): 367-70.

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Vining RF, McGinley RA. The measurement of hormones in saliva: possibilities and pitfalls. J Steroid Biochem 1987;27(1-3):81-94.

ECRI. Salivary Hormone Tests for Menopause and Aging in Adult Women (Hotline). April 2005.
Accessed September 2005.

ACOG Committee on Gynecologic Practice. Committee Opinion – Compounded Bioidentical Hormones. Obstetrics & Gynecology November 2005;106(5) Part 1.

NAMS POSITION STATEMENT. The 2022 hormone therapy position statement of The North American Menopause Society. Menopause: The Journal of The North American Menopause Society. 2022;29(No.7):767-94

This policy will be revised as necessary and reviewed no less than annually.

Devised: 12/09/05

Revised: 12/06

Reviewed: 12/07, 12/08, 12/09, 11/10, 11/11, 11/12, 11/13, 11/14, 11/15, 11/16, 10/17, 10/18, 10/19, 10/20, 10/21, 10/22, 10/23, 10/24, 10/25

CMS UM Oversight Committee Approval: 12/23, 12/24, 1/26

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.