PROVIDER POLICIES & PROCEDURES

OVA1® (MULTIVARIATE INDEX ASSAY)

The purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for OVA1® testing. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

OVA1®, also referred to as the multivariate index assay, was approved by the FDA in 2009 as a method for identifying patients likely to have malignant or benign adnexal masses, prior to surgery. The OVA1® test incorporates the biomarker values from five immunoassays that are variably expressed in ovarian cancer, CA 125, beta 2 microglobulin, transferrin, transthyretin, and apolipoprotein A1. Proprietary software called OvaCalc combines the values for each assay and uses an algorithm to generate an ovarian malignancy risk index score.

CLINICAL GUIDELINE

Coverage guidelines for OVA1® testing are made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an individual assessment of the member and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

OVA1® testing is considered experimental and investigational. The peer reviewed medical literature does not support OVA1® testing as having the specificity necessary to define its clinical use and therefore OVA1® testing is typically considered to be not medically necessary.

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE

Prior authorization of genetic testing is required. Requests for coverage of OVA1® testing will be reviewed in accordance with procedures in place for reviewing requests for genetic testing. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for OVA1® testing:

1. Fully completed State of Connecticut, Department of Social Services Genetic Testing Prior Authorization Request form;
2. Clinical information supporting the medical necessity of OVA1® testing; and
3. Other information as requested by CHNCT.

EFFECTIVE DATE

This Policy is effective for prior authorization requests for OVA1® testing for individuals covered under the HUSKY Health Program on or after August 1, 2018.

LIMITATIONS

Not Applicable

CODE:

Code	Description
81503	Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score

DEFINITIONS

1. **Current Procedural Terminology (CPT):** The most recent edition of a listing, published by the American Medical Association, of descriptive terms and identifying codes for reporting medical services performed by providers.
2. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
3. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
4. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
5. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
6. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
7. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
8. **HUSKY Plus Physical Program (or HUSKY Plus Program):** A supplemental physical health program pursuant to Conn. Gen. Stat. § 17b-294, for medically eligible members of HUSKY B in Income Bands 1 and 2, whose intensive physical health needs cannot be accommodated within the HUSKY Plan, Part B.
9. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to

attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.

10. **Prior authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

1. American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin: Evaluation and Management of Adnexal Masses, Number 174, November 2016.
2. ASPiRA LABs: About OVA1. Available at: http://www.vermillion.com/providers/intro-to-ova1/. Accessed on March 18, 2018.
3. Bristow, RE, Smith, A, Zhang, Z, et al. Ovarian malignancy risk stratification of the adnexal mass using a multivariate index assay. *Gynecologic oncology.* 2013 Feb;128(2):252-9.
4. Grenache DG, Heichman KA, Werner TL, et al. Clinical performance of two multi-marker blood tests for predicting malignancy in women with an adnexal mass. *Clinica chimica acta*; *international journal of clinical chemistry*. 2015 Jan 1;438:358-63.
5. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer. V.2.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf . Accessed on March 20, 2018.
6. National Institute of Health. National Cancer Institute. Genetics of Breast and Gynecologic Cancers (PDQ®). Available at: https://www.cancer.gov/types/breast/hp/breast-ovarian-genetics-pdq . Accessed on March 20, 2018.
7. Society of Gynecologic Oncology: Multiplex Serum Testing for Women with Pelvic Mass (May 2013).
8. Society of Gynecologic Oncology: Statement regarding OVA1 (September 2009).
9. Ueland FR, Desimone CP, Seamon LG, Miller RA, Goodrich S, Podzielinski I, et al. Effectiveness of a multivariate index assay in the preoperative assessment of ovarian tumors. *Obstet Gynecol* 2011;117:1289-1297.
10. UpToDate. Serum biomarkers for evaluation of an adnexal mass for epithelial carcinoma of the ovary, fallopian tube or peritoneum. Frederick Rand Ueland M.D., Andrew John Li M.D. Topic last updated April 24, 2017.
11. U.S. Food and Drug Administration. 510(k) Substantial Equivalence Determination Decision Summary: OVA1™ Test (K081754). Available at: http://www.accessdata.fda.gov/cdrh_docs/reviews/K081754.pdf. Accessed on March 20, 2018.

PUBLICATION HISTORY

Status	Date	Action Taken
Original publication	June 2018	Policy approved at the April 11, 2018 Medical Policy Review Committee meeting. Policy approved by the CHNCT Clinical Quality Subcommittee on June 18, 2018. Approved by DSS on June 25, 2018.
Review	May 2019	Reviewed without changes at the May 8, 2019 Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on June 19, 2019. Approved by DSS on June 21, 2019.