



TO: Physicians, Advanced Practice Registered Nurses (APRNs), Physician Assistants (PAs), Federally Qualified Health Centers (FQHCs), Outpatient Hospitals, and Laboratories

RE: New Clinical Guidelines: Coverage of the OVA1® (Multivariate Index Assay) Test

OVA1® (Multivariate Index Assay) Test

OVA1®, also referred to as the multivariate index assay, was approved by the Federal Drug Administration (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 Guidelines

The peer-reviewed medical literature does not support OVA1® testing as having the specificity necessary to define its clinical use. OVA1® testing will, therefore, be considered experimental and investigational and not medically necessary for HUSKY A, HUSKY B, HUSKY C, HUSKY D and Limited Benefit program members.

Services that are not medically necessary are not covered under Medicaid as set forth in the following Sections of the Regulations of Connecticut State Agencies:

- Section 17b-262-342(13) Goods and Services Not Covered Concerning Physicians' Services
- Section 17b-262-973(8) Services Not Covered Concerning Outpatient Hospitals
- Section 17b-262-998(2) Services Not Covered of the Requirements for Payment of Federally Qualified Health Centers
- Section 17b-262-612(a) Services Not Covered of the Requirements for Payment of Nurse Practitioner Services
- Section 17b-262-645(b)(4) Limitations on Covered Services of the Requirements for Payment of Laboratory Services

- Section 17b-262-531(g) Payment Limitations of the Requirements for Provider Enrollment

The new policy is available on the HUSKY Health Web site at: www.ct.gov/husky. To access the policy, click on **For Providers** followed by **Policies, Procedures and Guidelines** under the **Medical Management** menu item.