

Vermillion Announces Reimbursement Code Updates for Overa and OVA1

Description

AUSTIN, Texas, January 9, 2017 — Vermillion, Inc. (NASDAQ: VRML), a bio-analytical solutions company, today announced that the company and its wholly owned subsidiary, ASPIRA Labs, have received a Proprietary Laboratory Analyses (PLA) code (0003U) for Overa (MIA2G), Vermillion's second-generation FDA cleared Multivariate Index Assay test for determining the risk of ovarian cancer in a woman with a diagnosed pelvic mass, from the American Medical Association's (AMA) CPT® Editorial Panel.[\[1\]](#)

Overa, also known as "**Multivariate Index Assay, 2nd Generation**" (MIA2G), was cleared by the FDA in March 2016 and clinical validation was published in the *American Journal of Obstetrics and Gynecology* in July 2016.[\[2\]](#)

This new code is included in the first set of PLA codes to be released by the AMA to support the implementation of Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), which replaces the current Medicare Clinical Laboratory Fee Schedule with a new fee schedule based upon laboratory-reported private payer rates. PLA codes are proprietary clinical laboratory analyses that can be either provided by a single ("sole-source") laboratory or licensed or marketed to multiple providing laboratories (e.g. cleared or approved by FDA). Code 0003U, which is specific for Overa (MIA2G), was approved by the CPT Editorial Panel at its Q4 2016 meeting.

Additionally, earlier in 2016, OVA1 (MIA), Vermillion's first-generation Multivariate Index Assay, was included on the list of clinical diagnostic laboratory test procedure codes as one for which the Centers for Medicare & Medicaid Services would require reporting of private payer rates as part of the implementation of PAMA. Future Medicare pricing of OVA1 (MIA) is expected to be based *on the weighted median of final private payer rates from January through June 2016*. New rates are scheduled to take effect on January 1, 2018. Currently ASPIRA Labs reimbursement has been established by the local Medicare Administrative Contractor for OVA1.

In addition to reimbursement progress, Vermillion has also achieved important advancements on the treatment guidelines front:

- Multivariate Index Assay (MIA or OVA1) was recently added to the American College of Obstetricians and Gynecologists (ACOG) Guidelines (Practice Bulletin Number 174, dated November 2016) as a Level B recommendation. Level B recommendations state that the physician may use risk assessment tools such as Multivariate Index Assay (OVA1), to further evaluate the risk of malignancy and need for specialist referral in masses that do not meet Level A criteria for suspected malignancy based upon ultrasound evaluation alone.
- National Comprehensive Cancer Network (NCCN), Version 1.2016 (updated 8/26/16), stated, "The OVA1 test uses 5 biomarkers (including transthyretin, apolipoprotein A1, transferrin, beta-2 microglobulin, and CA-125) to assess who should undergo surgery by an experienced gynecological oncologist and who can have surgery in the community."

"We believe these new reimbursement updates for OVA1 and Overa, combined with the ACOG recommendation, NCCN inclusion, and the Society of Gynecologic Oncology position statement, now makes OVA1 the only pelvic mass risk assessment tool which has received recommendations and statements from all three medical societies which oversee ovarian cancer detection. We believe this will be key to driving positive medical policy and managed care contract decisions in 2017 and beyond," said Valerie Palmieri, President and CEO of Vermillion, Inc.

About Vermillion

Vermillion, Inc. is dedicated to the discovery, development and commercialization of novel high-value diagnostic and bio-analytical solutions that help physicians diagnose, treat and improve gynecologic health outcomes for women. Vermillion, along with its prestigious scientific collaborators, discovers, develops, and delivers innovative diagnostic and technology tools that help women with serious diseases. The company's initial in vitro diagnostic test, OVA1® (MIA), was the first FDA-cleared, protein-based In Vitro Diagnostic Multivariate Index Assay, and represented a new class of software-based liquid biopsy in vitro diagnostics. In March 2016 Vermillion received FDA clearance for Overa™, a Multivariate Index Assay 2nd Generation (MIA2G) test with significantly improved specificity and ease of use. For additional information, including published clinical trials, visit www.aspirawh.com.

About OVA1® and Overa™

- OVA1 (MIA) is a proprietary FDA-cleared blood test to help physicians assess the risk of ovarian cancer prior to surgery and as a result provide more effective referral of high risk patients to a specialist (gynecologic oncologist) for surgical treatment.
- The OvaCalc® proprietary algorithm combines five biomarker results into a single numerical "risk score" that stratifies patients into "higher risk" and "lower risk" when combined with clinical assessment.
- In two pivotal clinical trials, OVA1 (MIA) plus clinical impression detected 96% of all malignancies vs. 75% for clinical impression alone (CI). As a result, false negatives were reduced from 25% for CI, to 4% with OVA1 (MIA) plus CI, a reduction of 83%.

- In a study focused on early-stage cancer detection, 31% of cases were missed by clinical impression alone. This was reduced to 5% when OVA1 (MIA) was added to clinical impression, a reduction of 85%.
- Overa (MIA2G), cleared by FDA in March 2016, measures the levels of five proteins found in the blood and then uses a second-generation OvaCalc® algorithm to stratify risk. A woman's risk of cancer is measured by using a 0-10 scale with a single cut-off point of 5 eliminating the ambiguity in determining menopausal status. A high Overa score is not a diagnosis of cancer, rather it indicates an increased risk of malignancy when used as intended.
- **PRECAUTION:** OVA1® and Overa tests should not be used without an independent clinical/radiological evaluation and are **not** intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of OVA1® or Overa carries the risk of unnecessary testing, surgery, and/or delayed diagnosis.

Forward-Looking Statements

This press release contains forward-looking statements, as that term is defined in the Private Litigation Reform Act of 1995, that involve significant risks and uncertainties, including statements regarding the potential impact of the receipt of a PLA code for Overa (MIA2G), statements regarding the potential impact on pricing of the CLFS rules implemented under PAMA and the anticipated timing of such impact and statements regarding the potential impact of OVA1's (MIA's) recent inclusion in ACOG clinical management guidelines and NCCN update. Words such as "may," "expects," "intends," "anticipates," "believes," "estimates," "plans," "seeks," "could," "should," "continue," "will," "potential," "projects" and similar expressions are intended to identify forward-looking statements. The forward-looking statements contained in this press release are based on Vermillion's expectations as of the date of this press release. A variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in such forward-looking statements, including changes to interpretations of existing laws and regulations and other factors that are described in Vermillion's Form 10-K for the year ended December 31, 2015 and Form 10-Q for the quarter ended March 31, 2016 as filed with the Securities and Exchange Commission. Vermillion expressly disclaims any obligation to update, amend or clarify any forward-looking statements to reflect events, new information or circumstances occurring after the date of this press release, except as required by law.

[1] <https://www.ama-assn.org/sites/default/files/media-browser/public/physicians/cpt/cpt-pla-codes-long-v2.pdf>

[2] : Coleman RL, Herzog TJ, Chan DW, et al. Validation of a second-generation multivariate index assay for malignancy risk of adnexal masses. *Am J Obstet Gynecol* 2016;215:82.e1-11.