ASPiRA LABs Announces Provider Status with Medi-Cal

Description

Expanding OVA1® Access to Over 12 Million Beneficiaries
AUSTIN, Texas, March 6, 2017 — ASPiRA LABs, a Vermillion company (NASDAQ: VRML), today announced it has attained out-of-state provider status with Medi-Cal, California's Medicaid program, for OVA1®/Multivariate Index Assay (MIA). ASPiRA Labs is the sole source provider for OVA1 (MIA), an FDA cleared, ACOG recommended[1] ovarian cancer risk assessment test. With ASPiRA Labs' out-of-state provider status with Medi-Cal, OVA1 (MIA) is now available to over 12 million Medi-Cal beneficiaries, representing approximately a third of the covered lives in California.

"We are pleased to announce our new Medi-Cal provider status for OVA1 (MIA)," said Valerie Palmieri, President and CEO of Vermillion, Inc. "This new status is an expansion to our prior Medi-Cal coverage and is key to reaching the entire Medicaid base, as well as expanding OVA1 (MIA) access in the state with the largest U.S. population. It should also create additional opportunities with healthcare systems and other medical insurers in the California market."
"The mortality rate of ovarian cancer has not changed in 40 years, even following the introduction of CA125. Two thirds of women today with ovarian cancer do not receive the initial appropriate treatment for ovarian cancer. But with our new Medi-Cal out-of-state provider status, millions of women in the State of California will now have access to technology that may change this paradigm."
See website to review clinical studies **showing OVA1's (MIA's) performance over CA125:**
https://aspiralsc.wpengine.com/ova1-clinical-studies/

About OVA1® (MIA) and Overa™ (MIA2G)

- OVA1 (MIA) is a proprietary FDA-cleared blood test designed to help physicians assess the risk of ovarian cancer prior to surgery, facilitating more effective referral of high risk patients to a specialist (gynecologic oncologist) for surgical treatment.
- OVA1 (MIA) now has an ACOG Level B recommendation for the Evaluation and Management of Adnexal Masses (ACOG Practice Bulletin #174, November 2016).
- 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 assessment (ca) detected 94% of all malignancies vs. only 77% for CA125 plus ca,[2] and OVA1 (MIA) plus ca detected 95.3% of all malignancies vs. only 80% for CA125 plus ca.[3]
- In a study focused on early-stage ovarian 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%.[4]

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- Overa (MIA2G) 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.
- OVA1 (MIA) has shown clinical utility in increasing the rate of referrals of malignant adnexal masses to gynecologic oncologists. The increased involvement of specialists may lead to increased adherence to National Comprehensive Cancer Network guidelines which includes surgical treatment by a gynecologic oncologist, which is associated with improved cancer outcomes, including overall survival. In a study focused on specialist involvement in ovarian cancer treatment, 94% of patients with an elevated-risk OVA1 (MIA) result who had primary ovarian malignancies were appropriately referred to a gynecologic oncologist.[5]
- 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.

[1] American College of Obstetricians and Gynecologists. ACOG Practice Bulletin #174. Evaluation and Management of Adnexal Masses. Obstet Gynecol. 2016; 128:e210-26.

[2] Ware Miller R, Smith A, DeSimone CP, Seamon L, Goodrich S, Podzielinski I, et al. Performance of the American College of Obstetricians and Gynecologists' ovarian tumor referral guidelines with an index assay. Obstet Gynecol 2011 Jun; 117(6):1298-306.

[3] Longoria TC, Ueland FR, Zhang Z, Chan DW, Smith A, Fung ET, et al. Clinical performance of a multivariate index assay for detecting early-stage ovarian cancer. Am J Obstet Gynecol 2014 Jan; 210(1):78.e1-9.

[4] Bristow RE, Smith A, Zhang Z, Chan DW, Crutcher G, Fung ET, et al. Ovarian malignancy risk stratification of the adnexal mass using a multivariate index assay. Gynecol Oncol 2013 Feb; 128(2):252-9.

[5] Eskander RN, Carpenter BA, Wu HG, Wolf JK. The clinical utility of an elevated-risk multivariate index assay score in ovarian cancer patients. Curr Med Res Opin 2016 Jun; 32(6):1161-5.

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