Vermillion Announces Publication of Foundational Health Economics Study

Description

Vermillion Announces Publication of Foundational Health Economics Study
Potential savings of up to $0.17 PMPM for Commercially Insured and $0.05 PMPM for Medicare

AUSTIN, Texas, November 16, 2017 — Vermillion (NASDAQ: VRML) announced today the acceptance and publication of a novel paper, "Economic Impact of Increased Utilization of Multivariate Assay Testing to Guide the Treatment of Ovarian Cancer: Implications for Payers" in the journal ***American Health and Drug Benefits*.**
The paper details the base case of a budget impact model that dynamically tracks the effect of OVA1 adoption in lieu of CA125 in the appropriate patient population on overall cost, both at a plan and per member per month (PMPM) level. Claims data from a total of over 92,000 health plan members, comprising over 48,000 commercially insured members and 44,000 Medicare beneficiaries, were used in the development of the model. Sensitivity analysis revealed potential savings of up to $0.17 PMPM for commercially insured patients and up to $0.05 for Medicare beneficiaries. These results of the budget impact model base case support the use of OVA1 instead of CA125, by indicating that cost-savings can be achieved, while reaping the clinical benefits of improved diagnostic accuracy, early disease detection, and reductions in multiple, and possibly non-medically necessary, referrals to gynecologic oncologists.
"Practicing in today's healthcare environment requires doctors to provide the highest standard of care that remains cost effective and improves evidence based outcomes," stated Dr. Burton Brodsky, Director of Minimally Invasive Surgery, Section Chief Gynecological Services, and Assistant Clinical Professor at the University of Toledo, who is also one of the co-authors of this paper. "OVA1 can accomplish all these important health care parameters for women having surgery for a pelvic mass".
Ovarian cancer will affect over 22,000 U.S. women in 2017 (1), greater than 200,000 women globally (2), and has the lowest survival rate of all gynecological cancers, with a 5 year survival rate of less than 50% (1). Earlier detection and proper care pathways increase the chance of survival and patient outcomes(3-5), which has been the primary mission of Vermillion/ ASPiRA Labs since OVA1 (MIA) was first launched in 2010. The appropriate referral of patients who are at high risk for ovarian cancer is necessary for optimal outcomes; however, referral of benign cases can increase wait times for a specialist visit and often, if not medically necessary, can increase anxiety and other burdens to the patient. Using all preoperative information available to the clinician, which includes symptoms, family history, physical exam, ultrasound findings, and OVA1 (MIA) results can facilitate the appropriate triage of patients with a pelvic mass either to the gynecologic oncologist or to remain with their OB/Gyn provider for care and surgery.
"Vermillion is dedicated to working towards improving the lives and outcomes for women with ovarian cancer while doing our part to keep appropriate cost of care effective for everyone. We are very encouraged by the results of this latest study." Stated Marra Francis, MD, FACOG, CMO of Vermillion.
OVA1 (MIA) is now considered a Level B Recommendation by ACOG(6). Based on its support by ACOG, NCCN update and SGO positive position statement, OVA1 (MIA) can be the physician's first choice in

biomarker panels to best triage their pelvic masses to the most appropriate care pathway. There is no other comparable technology on the market today.

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.

1. www.cancer.gov/types/ovarian
2. www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/ovarian-cancer-statistics
3. Chan JK, Kapp DS, Shin JY, et al. Influence of the gynecologic oncologist on the survival of ovarian cancer patients. Obstet Gynecol. 2007;109:1342Y1350.
4. Engelen MJ ,Kos HE,Willemse PH,etal. Surgery by consultant gynecologic oncologists improves survival in patients with ovarian carcinoma. Cancer. 2006;106:589Y598.
5. Vernooij F,Heintz P,Witteveen E,etal.The outcomes of ovarian cancer treatment are better when provided by gynecologic oncologists and in specialized hospitals: a systematic review. Gynecol Oncol. 2007;105:801Y812
6. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin. Management of adnexal masses. Obstet Gynecol. 2016; 128: e210-26.