

A Study of



Senate Bill S-132

A Report to the New Jersey State Senate by the

Mandated Health Benefits Advisory Commission



May 1, 2007

Jon S. Corzine
Governor

Steven M. Goldman
Commissioner
Department of Banking and Insurance

Table of Contents

Introduction.....	1
What S-132 Requires.....	1
Other States.....	2
Ovarian Cancer.....	3
Diagnosis.....	3
CA-125.....	5
Recommendations of Professional Organizations.....	5
Advances in Screening.....	6
Cost Analysis.....	6
Conclusion.....	7

Appendix I Staff Cost Analysis of S-132

Introduction.....	1
Summary of S-132.....	1
Cost Analysis.....	2
Conclusion.....	3

Appendix II A Report to the New Jersey Mandated Health Benefits Advisory Commission, Review and Evaluation of Senate Bill S132 - An Act Concerning Health Benefits Coverage for Ovarian Cancer Screening, by Marsh Actuarial Consulting, Inc.

Introduction

On January 16, 2007 the Mandated Health Benefits Advisory Commission (Commission) was asked to issue a report on Senate Bill 132 (S-132). The Commission undertook the study with the understanding that it is charged by law with investigating the many facets of the impact of S-132. With this in mind and considering the limited time and resources of the Commission and Department staff, an actuarial firm with experience in such investigations, Marsh & Associates, was engaged to study this bill and provide an estimate of the impact of S-132 on health insurance premiums. (The Marsh & Associates study is submitted as Appendix II to this report). The Commission understands that, as a general rule, the Legislature wants these studies to emphasize the financial impact on the insurance market, including the impact on price and on the availability of necessary medical services. However, in the case of S-132, the Commission felt that the question of the medical appropriateness of wide-spread screening was more important than the question of cost.

The Commission received comments on S-132 from the New Jersey Association of Health Plans.

What S-132 Requires

Senate Bill 132 applies to the state regulated insurance market and the State Health Benefits Plan (SHBP). The regulated insurance market includes individual and group contracts or policies sold in New Jersey by hospital, medical and health service corporations (e.g. Horizon Blue Cross Blue Shield), by insurance companies, and by health maintenance organizations (HMOs). The bill applies to contracts and policies sold in the Individual Health Coverage (IHC), Small Employer Health (SEH) and large group markets. In round figures, there are 2.5 million people covered by the state regulated market and 800,000 covered by the NJ SHBP of the 8.7 million people in New Jersey.

The bill requires policies or contracts issued by the above entities that cover hospital and medical expenses to provide benefits for medically necessary expenses incurred in screening for ovarian cancer for symptomatic women or women at risk of ovarian cancer, including an annual pelvic examination, an ultrasound and blood testing for cancer markers. The bill requires the benefit to be provided to the same extent as for any other condition covered by the contract or plan.

The wording of the bill makes its precise intent unclear. Screening refers to testing for a condition before a person has symptoms. Carriers advise that they cover pelvic examinations, ultrasounds, and blood testing for cancer markers for women with

symptoms of ovarian cancer. They also cover additional diagnostic procedures (including ones involving surgery) if indicated by the initial testing.

Carriers indicate that they do cover screening when risk is indicated by factors such as family history or presence of a characteristic genetic mutation (see the discussion of the BRCA1 and BRCA2 mutations below). However, this screening is likely only indicated for asymptomatic women when risk is relatively high.

The Commission, therefore, interprets the bill as mandating screening for asymptomatic women who have a small, but positive, risk of ovarian cancer. These and other diagnostic procedures are already routinely covered for symptomatic women or women of higher risk.

Other States

Five states have enacted laws mandating coverage of ovarian cancer tests for women who are at risk of ovarian cancer and/or for women who have ovarian cancer. Four of the statutes include specific reference to CA-125 surveillance or monitoring. See 18 Del. C. sec. 3338 and 3555 (requires coverage of CA-125 monitoring of women with ovarian cancer subsequent to treatment), O.C.G.A. sec. 33-24-56.2 (requires coverage of surveillance tests for women age 35 and older at risk for ovarian cancer, at risk defined as a family history of one or more first or second degree relatives with ovarian cancer, of clusters of female relatives with breast cancer, or of nonpolyposis colorectal cancer, or testing positive for BRCA1 or BRCA2 mutations, surveillance defined as CA-125 serum marker testing, transvaginal ultrasound and pelvic examination.), 215 Ill. Comp. Stat. 5/356u and 125/4-6.5 (requires coverage of surveillance tests for ovarian cancer for female insureds at risk for ovarian cancer, at risk defined as one or more first degree relatives with ovarian cancer, a family history of clusters of female relatives with breast cancer, a family history of nonpolyposis colorectal cancer or a positive test for BRCA1 or BRCA2 mutations, surveillance tests defined as tests for CA-125 serum tumor markers, transvaginal ultrasound and pelvic examination), Minn. Stat. sec. 62A.30 (requires coverage of surveillance tests for women at risk for ovarian cancer defined as a family history or testing positive for BRCA1 or BRCA2 mutations, surveillance test includes annual screening using CA-125 serum tumor marker testing, transvaginal ultrasound, pelvic examination or other proven cancer screening tests), N.C. Gen. Stat. sec. 58-3-270 (requires coverage of surveillance tests for women 25 and older at risk for ovarian cancer, at risk defined to mean a family history or testing positive for hereditary ovarian cancer syndrome, surveillance test defined as annual screening using transvaginal ultrasound and rectovaginal pelvic examination).

Ovarian Cancer

Ovarian cancer is a disease in which malignant cells form in the tissue of the ovaries. It is the 7th most common cancer diagnosed among women and the 4th leading cause of cancer death among women. Although there is a low incidence of ovarian cancer in the general population (age-adjusted incidence of 17 per 100,000 women), ovarian cancer causes more deaths than any other cancer of the female reproductive system. Despite being only 1/10 as common as breast cancer, ovarian cancer is three times more lethal. Less than half the women with ovarian cancer survive five years after diagnosis. In 2007, an estimated 22,430 women in the United States will be diagnosed with ovarian cancer and an estimated 15,280 women in the United States will die from the disease. In New Jersey, 800 women are diagnosed with ovarian cancer and more than 500 die from the disease each year.

Ovarian cancer is classified by the cell type of the tumor. Epithelial ovarian cancer occurs on the surface of the ovary in the epithelial cells. About 85-90% of ovarian cancers are epithelial ovarian cancers. Less common forms of ovarian cancer include germ cell tumors, ovarian stromal tumors and mixed mullerian tumors.

There are four stages of ovarian cancer. In stage 1 the cancer is limited to one or both ovaries. In stage 2 the cancer has grown onto or into the other organs within the pelvis. In stage 3 the cancer has spread either beyond the pelvis to the lining of the abdomen or to the lymph nodes. In stage 4 the disease has spread to distant sites such as the inside of the liver, the lungs, or to other organs outside the pelvis or abdomen.

Diagnosis

Ovarian cancer is difficult to diagnose because its symptoms are vague. They include abdominal swelling, unusual vaginal bleeding, pelvic pressure, back pain, leg pain and digestive problems such as gas, bloating, indigestion and long term stomach pain. Most patients are asymptomatic in the early stages of the disease and usually do not present until the disease has advanced to stage 3 or 4.

Risk factors for ovarian cancer include age (usually over 50, highest risk over 60), extended and uninterrupted menses including nulliparity, use of fertility drugs, hormone therapy post-menopause and a family history of ovarian, breast or colorectal cancer. There is also a relationship between the BRCA1 and BRCA2 (breast cancer 1 and breast cancer 2) gene mutations and ovarian cancer; women with either mutation have a 23% chance of developing ovarian cancer by age 30 and a 63% chance by age 70. BRCA1 and BRCA2 genes control cell growth and division. When there is a mutation in one of these genes, cell growth may become uncontrolled and cancer develops. The likelihood that breast or ovarian cancer is related to a BRCA1 or BRCA2

mutation is highest where there is a family history of multiple cases of breast cancer, instances of both breast and ovarian cancer, one or more family members with two primary cancers or an Ashkenazi (Eastern European) Jewish background. It is estimated that 5 - 10% of breast and ovarian cancers are due to inherited forms of the disease.

Testing for BRCA1 and BRCA2 mutations involves a blood test that costs from several hundred to several thousand dollars. Carriers cover testing for BRCA1 and BRCA2 mutations for patients with no personal history of breast or ovarian cancer only where they are at high risk, such as where they have a first or second degree relative with a mutation, have three or more first or second degree afflicted relatives, have one or more first or second degree relatives with multiple primary or bilateral breast cancers, or who have one or more male relatives with breast cancer. The United States Preventive Services Task Force (USPSTF) recommends against routine BRCA tests for women whose family history is not associated with an increased risk for BRCA1 or BRCA2 mutations. The USPSTF recommends that women who do have such history be referred for genetic counseling and evaluation for BRCA testing. Prophylactic oophorectomy (removal of healthy ovaries) decreases risk in women with a BRCA1 or BRCA2 mutation.

Factors that may decrease the risk of developing ovarian cancer include use of oral contraceptives, giving birth, breast feeding and having a tubal ligation or hysterectomy. Prophylactic oophorectomy (removal of healthy ovaries) decreases risk in women with a BRCA1 or BRCA2 mutation.

There is no direct evidence that women whose ovarian cancer is detected early have lower mortality than do women whose disease is more advanced when diagnosed although indirect evidence supports this conclusion. Studies have shown that the most significant factor in determining outcome of patients with advanced ovarian cancer is the size of the tumor following treatment. Since surgery and chemotherapy for ovarian cancer appear to be more effective in reducing tumor size when the disease is detected early, an early diagnosis is felt to increase survival rates.

Although there is no reliable screening test for the disease, several methods are used to detect ovarian cancer including a blood test for CA-125, ultrasound and a pelvic examination. The effectiveness of a pelvic examination for the detection of ovarian cancer is low. Small early stage tumors are often not detected by palpation because of the deep anatomic location of the ovaries. Cancers found through pelvic examination are usually advanced. The effectiveness of ultrasound is limited by its high rate of false positive results. A positive screening test, which should involve the above described procedures, requires a complete diagnostic work-up and an exploratory laparoscopy and/or laparotomy for a diagnosis. In laparoscopy, a thin lighted tube is inserted through a small incision in the lower abdomen and the ovaries, other pelvic organs and tissue around the bile duct are viewed and tissue can be removed for biopsy. Such invasive abdominal surgery carries a risk of complications.

CA-125

Cancer Antigen-125 (CA-125) is a protein found at elevated levels in ovarian cancer cells as compared to normal cells. CA-125 is produced on the surface of the cells and is released in the blood stream. Levels of CA-125 in the blood are used routinely to check whether a patient's ovarian cancer is responding to medical treatment, is continuing to grow, or is returning following surgery. A CA-125 test result of greater than 30 U/ml is generally accepted as being elevated.

Studies have shown that CA-125 produces an extremely high number of false positive results. Several conditions can cause false positive results of a CA-125 test, including endometriosis, uterine fibroids, benign ovarian cysts, first trimester pregnancy and pelvic inflammation. A study of 5,500 women older than 40 who used CA-125 testing showed the following results.¹

A specificity of 96.9% - meaning that the probability of testing negative when a person does not have the disease is high

A sensitivity of 50% - meaning that the probability of testing positive when you do have the disease is one half

A positive predictive value of 3.4% - meaning that only 3% of the patients with positive test results have ovarian cancer and 97% have a false positive result

A study by the British Health Technology Assessment program estimated the positive predictive value of the CA-125 as 2%, meaning that 98% of the women with positive results will not have ovarian cancer.²

Recommendations of Professional Organizations

No major medical organization recommends CA-125 testing for ovarian cancer screening in asymptomatic women. The United States Preventive Services Task Force (USPSTF) recommends against routine screening for ovarian cancer. The USPSTF explains its reasoning thus:

¹ Specificity is the probability of testing negative when you do not have the condition, sensitivity is the probability of testing positive when you do have the condition, positive predictive value is the proportion of patients with positive test results who are correctly diagnosed, and negative predictive value is the proportion of patients with negative test results who are correctly diagnosed.

² Bell R, Petticrew M, Luengo S, Sheldon TA. Screening for ovarian cancer: a systematic review. Health Technology Assessment (Winchester, England). 1998.

The USPSTF found fair evidence that screening with serum CA-125 level or transvaginal ultrasound can detect ovarian cancer at an earlier stage than it can be detected in the absence of screening; however, the USPSTF found fair evidence that earlier detection would likely have a small effect, at best, on mortality from ovarian cancer. Because of the low prevalence of ovarian cancer and the invasive nature of diagnostic testing after a positive screening test, there is fair evidence that screening could lead to important harms. The USPSTF concluded that the potential harms outweigh the potential benefits.

Screenings of asymptomatic women for ovarian cancer is not recommended by the American College of Preventive Medicine, American Cancer Society, the American College of Obstetricians and Gynecologists, and the American College of Physicians.

For women at risk of developing ovarian cancer, the NIH consensus conference recommends annual CA-125 measurement, pelvic examinations and transvaginal ultrasound. The USPSTF and the Canadian Task Force on Periodic Health Examination find insufficient evidence to define or screen high risk women. The American College of Preventive Medicine states that screening of women with familial cancer syndrome may be appropriate but direct evidence of effectiveness is lacking. It therefore recommends counseling high risk women about the potential benefits and harms of screening.

Advances in Screening

As this report was being prepared, researchers from Yale University presented research on a blood test that measured levels of six proteins. In a group of volunteers, the test had a sensitivity of 97.5% and a specificity of 99.7%. Because of the extremely low rate of incidence of ovarian cancer in the general population, this still yields a positive predictive value of “only” 12.6%, meaning that there are approximately 7 false positives for every true positive. However, this is a marked improvement over the positive predictive values of 2%-3.4% mentioned above in connection with CA-125.

We do not know when, if at all, this test will become commercially available. We also do not have an estimate of the cost. However, it is possible that this development, or the introduction of some other screening test in the near future, will make this current report out-of-date.

Cost Analysis

DOBI staff prepared a separate report on the estimated cost of this mandate. The staff cost analysis is included as Appendix I to this report. Depending on interpretation of the population considered at risk (and eligible for screening) and the

tests to be covered, the impact of this bill on cost could range from nothing (current carrier practices are consistent with the requirements of the bill) to about 7% of premium (testing for the BRCA-1 and -2 mutation mandated for all women 50 and older). However, as stated below, the Commission does not feel that cost is the determining factor in the evaluation of this proposed mandate.

In addition, Marsh & Associates was engaged to study the cost impact of the mandate. Their results were consistent with the DOBI staff results; however, they concluded that eliminating carrier medical necessity review (relying solely on the physician's determination) could increase premiums by 0.23% (23 one-hundredths of a percent). The Marsh Report is submitted as Appendix II of this report.

Conclusion

This Commission understands the intent of the bill that health coverage should not create barriers to medically indicated diagnostic testing, or screening, for ovarian cancer. Many characteristics of this disease (its low incidence rate, its lack of clear early symptoms, and its case-mortality rate), would seem to support testing when this disease is suspected or there is high risk.

However, the subject of this bill is an area where the Commission could find little or no disagreement between the practice standards of the medical profession and the reimbursement standards of carriers. Carriers, both in their stated policy and their claims practices, appear willing to reimburse necessary testing for symptomatic individuals, and further in some cases reimburse for screening for individuals at risk. In cases of very high risk, even expensive genetic testing is reimbursed. Therefore, it appears that the intent of this law is already being met.

Furthermore, the Commission has a serious concern that the legislature not appear to endorse levels or types of screening that exceed the current recommendations of the medical profession. The cost of this screening is not a significant concern. (The current level of such screening could be multiplied by 10 without having a material impact on cost.) Rather, the Commission is concerned that widespread screening, using the current tests available which generate many false positives (indications of the disease when no disease is present) requiring follow-up surgery, will result in, at best, unnecessary worry and inconvenience, and, at worst, additional serious injury and death resulting from surgical complications.

However, the Commission notes the possibility (discussed above) that an accurate blood test for ovarian cancer screening developed at Yale University could soon be available. If such a test were available with an acceptable positive predictive value, the Commission expects that both the recommendations of the medical profession on screening, and the coverage provided by health carriers, would change to make this test widely available. If the findings of the medical profession and carriers are consistent, then there should be no need for a mandate such as S-132 to assure necessary screening.

APPENDIX I

STAFF COST ANALYSIS OF S-132

Introduction

On January 16, 2007 the Mandated Health Benefits Advisory Commission (Commission) was asked to issue a report on Senate Bill 132 (S-132). The Commission undertook the study with the understanding that it is charged by law with investigating the many facets of the impact of S-132. The Commission understands that, as a general rule, the Legislature wants these studies to emphasize the financial impact on the insurance market, including the impact on price and on the availability of necessary medical services. However, in the case of S-132, the Commission felt that the question of the medical appropriateness of wide-spread screening was more important than the question of cost. This separate cost analysis must be considered in the context of the overall Commission discussion of screening for ovarian cancer.

This preliminary cost analysis was carried out by Department Staff. Because of limits on time and expertise, the firm of Marsh & Associates was retained. This firm's report is submitted separately. Its general conclusions on cost impact are consistent with those reached by staff.

Summary of S-132

Senate Bill 132 applies to the state regulated insurance market and the State Health Benefits Plan (SHBP). In round figures, there are 2.5 million people covered by the state regulated market and 800,000 covered by the NJ SHBP of the 8.7 million people in New Jersey.

The bill requires carriers to cover medically necessary expenses incurred in screening for ovarian cancer for symptomatic women or women at risk of ovarian cancer, including an annual pelvic examination, an ultrasound and blood testing for cancer markers.

Technically, screening refers to testing for a condition before a person has symptoms. Carriers advise that they cover pelvic examinations, ultrasounds, and blood testing for cancer markers for women with symptoms of ovarian cancer. They also cover additional diagnostic procedures (including ones involving surgery) if indicated by the initial testing. Carriers indicate that they do cover screening when risk is indicated by

factors such as family history or presence of a characteristic genetic mutation. However, this screening is likely only indicated for asymptomatic women when risk is relatively high.

Cost Analysis

DOBI staff requested cost information on diagnosis or treatment of ovarian cancer from the larger New Jersey health carriers. MHBAC staff also requested similar information from the New Jersey State Health Benefits Plan (NJSHBP). DOBI received responses from 4 carriers; 2 of these responses could provide only limited information. Some data on the NJSHBP was included in the carrier response. (Unfortunately, carrier claim systems are not designed as research tools, and it is sometimes difficult for carriers to obtain information about specific procedures or diagnoses.)

The current practice of carriers is to cover testing (including the tests mentioned in the bill) for people who exhibit symptoms. Some testing is also covered for people who are considered at high risk. Risk factors include family history, previous cancer, or presence of the BRCA-1 or 2 genetic mutation. When indicated by other risk factors, testing for the mutations is covered.

The easier diagnostic tests (CA-125 and Ultrasound) appear relatively infrequently in connection with a diagnosis of ovarian cancer – perhaps 50 per 100,000 covered lives for CA-125 and 25 per 100,000 covered lives for ultrasound. Each procedure seems to cost around \$200, at least when provided in-network. A positive indication from these tests requires a surgical procedure: laparoscopy or laparotomy. These procedures (in connection with ovarian cancer) have a frequency of about 2 per 100,000 covered lives and an average cost of about \$1,500. The total current cost of this testing is about 20 cents per year per covered person.

One possible result of S-132 could be an increase in the number of asymptomatic women deemed to be at risk for whom testing is indicated. Even if the amount of testing were multiplied by 10, the cost, \$2 per year, would be about 5 basis points (5 one hundredths of a percentage point.) of the annual premium. (A comparable analysis by Marsh & Associates suggested a slightly higher estimate, of 23 basis points or .23% of premium.)

Note that these low costs for CA-125, ultrasound, and diagnostic surgery refer only to tests and procedures done where ovarian cancer is a possible diagnosis. We believe these tests are performed more frequently for other possible diagnoses.

As a conservatively high cost estimate, we considered the possibility that S-132 would lead to screening for a much wider population. For example, assume that 10% of covered people are women between the ages of 50 and 65, and that all women in this age group deemed to be at risk and needing screening. The screening costs would be significant: For ultrasound and CA-125, the cost could be \$400 for each woman in the age group, or \$40 per covered person per year (assuming that 10% of covered people

are tested). In addition, there would be a cost \$4 per covered person per year for the surgical follow up (assuming that the testing generated the same proportion of positives requiring follow up as is presently the case.) This cost would be about 1.2% of the average cost per covered person.

Out of an affected population of 3.3 million (commercial market + NJSHBP) this program would result in about 8,800 surgical procedures to confirm or deny the indication of the less invasive testing. Since every surgery runs the risk of infection or worse, there could be illness and death related to the testing regime. So, we want to be clear that this cost estimate is hypothetical only, and that the screening to this extent is contrary to current recommendations.

Although the law does not refer specifically to testing for BRCA mutations, such a test could be considered medically necessary screening, under the law, for at risk women. This test, which costs about \$2,500 currently, is covered by insurers in some cases, presumably where family history or medical history strongly indicates the possibility. This test for 10% of the covered population would increase the annual cost of coverage by \$ 250, or about 7% on the average. Not only would this make coverage more expensive on the average; it could cause carriers who are allowed to age rate to modify their rating systems to place this extra cost burden on older women or groups with a high percentage of older women.

Conclusion

The cost associated with this bill depends on the interpretation of what it means to be at risk, and what tests, other than those explicitly stated in the bill, should be covered. Under a conservative interpretation, the requirements of the bill are already met, because carriers cover all medically necessary testing for women who are symptomatic or at risk. Even if the number of women who were considered risky and tested were multiplied by 10, the impact on costs would be insignificant.

On the other hand, if the bill were interpreted to require routine screening (CA-125 blood test and ultrasound) for all women 50 and over, there could be a 1.2% increase, which is material, in average premiums. The Commission report will discuss the medical indications against such wide-spread screening.

Finally, this bill could be interpreted to require testing for the BRCA-1 and -2 mutations among women at risk. If the population at risk is defined narrowly, then the cost impact should be small. (Carriers already pay for this test in very limited situations.) However, if the bill were interpreted, for example, to mandate coverage of BRCA-1 and -2 testing for all women 50 and over, the cost impact could be a 7% increase in average premiums.

Recently, researchers have reported on blood test that has a higher degree of accuracy than CA-125. This test is not commercially available. We have no basis for estimating the cost impact of this test should it become available.

Marsh Actuarial Consulting, Inc.

A Report to the New Jersey Mandated Health Benefits Advisory Commission

**Review and Evaluation of Senate Bill S132
An Act Concerning Health Benefits Coverage for Ovarian Cancer Screening**

Prepared by:

**James MacDougall, FSA, MAAA
Marsh Actuarial Consulting, Inc.**

Table of Contents

Introduction3

Ovarian Cancer and Screening Methods4

Cost of Ovarian Cancer Screening4

Stages of Ovarian Cancer5

The case for early detection5

Types of Screening5

Cost of Screening6

Procedures involved in Ovarian Cancer Screening9

Development of Cost Estimate 10

Introduction

The New Jersey Legislature has requested the New Jersey Mandated Health Benefits Advisory Commission to conduct a review of Senate Bill 132.

Senate Bill 132:

A hospital service corporation contract that provides hospital and medical expense benefits and is delivered, issued, executed or renewed in this State pursuant to P.L. 1938, c.366 (C. 17:48-1 et seq.), or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance, on or after the effective date of this act, shall provide coverage for medically necessary expenses incurred in screening for ovarian cancer for symptomatic women or women at risk of ovarian cancer, which coverage shall include, but is not limited to, an annual pelvic examination, an ultrasound and blood testing for cancer markers. The benefits shall be provided to the same extent as for any other condition under the contract.

This section shall apply to those hospital service corporation contracts in which the hospital service corporation has reserved the right to change the premium.

There are several sections to the Bill, which replace the above words “hospital service corporation” to “medical service corporation”, “health Service Corporation”, “individual insurance”, “group insurance”, “small employer health plan” and “individual health benefits plan”.

The Commission understands that the Legislature specifically desires a discussion of the implications of this bill on the insurance market, including impact on price and on the availability of necessary medical services. This report explores some of the issues surrounding screening for ovarian cancer, the issues of determining medically necessary and studies the increased costs associated with screening. Additionally, this report discusses new technologies in ovarian cancer screening advances, but does not quantify these new screening methods. This report is not intended to evaluate the societal impact or the actual premiums charged to employees under group health benefit plans, since employee cost sharing may increase to offset the costs of mandates. The increased cost to individual health plan subscribers may also be mitigated through increased cost sharing provisions. Therefore, when evaluating premium increases, there is an implicit assumption that all costs are passed on to employees and individuals covered under their benefit plans.

Ovarian Cancer and Screening Methods

Ovarian cancer has a prevalence of 50/100,000 women and an annual incidence rate of 12.9/100,000 women and an estimated 14.4/100,000 women annual incidence rate in New Jersey(1). In the absence of a family history of ovarian cancer, lifetime risk of ovarian cancer is 1/70. Risk factors include familial cancer syndromes (breast cancer) and family history of ovarian cancer (1.4% lifetime risk with no affected relatives, 5% with one affected relative, and 7% with two affected relatives)(2). 95% of all ovarian cancers occur in women without risk factors – this is due to the low incidence of ovarian cancer in general. Ovarian cancer is the fifth leading cause of death by cancer for women in the United States.

Under a number of conditions women face a higher than average risk of developing ovarian cancer. Including:

- Women over 40;
- Women who have never been pregnant;
- Women who are identified with a specific mutation in a gene called BRCA1 or BRCA2 (short for breast cancer 1 and breast cancer 2 respectively);
- Women whose mothers, sisters or daughters have had ovarian cancer; although most affected women do not have a family history of ovarian cancer,
- Women with a history of ovarian, breast, uterine or colon cancer on either side of her family
- Women with a personal history of breast, uterine or colon cancer; and
- Smoking

Conditions that reduce the risk of ovarian cancer include:

- Pregnancy and childbirth
- Oral contraceptives taken for 5 or more years (ovarian cancer has been declining in the past 20 years and some believe that increased use of oral contraceptives is a contributing factor to the decline).
- Hysterectomy
- Removal of ovaries

Symptoms:

- Feeling bloated
- Abdominal, pelvic or back pain
- Excessive fatigue
- Frequent/Urgent urination

(1) U.S. Cancer Statistics Working Group. *United States Cancer Statistics: 2003 Incidence and Mortality*. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; 2006.

(2) Screening Asymptomatic Women for Ovarian Cancer:
American College of Preventive Medicine Practice Policy Statement
Rebecca Ferrini, MD, MPH

(3) HARVARD WOMEN'S HEALTH WATCH
May 2000, pp. 2-4

Stages of Ovarian Cancer:

Ovarian cancer is divided into four stages, and treatment decisions vary based on the stage diagnosed. Cancer stage is a shorthand way of describing location – the higher the stage, the further the spread of the disease.

The stages are following:

- Stage I: Cancer is confined to one or both ovaries. When cancer is diagnosed at this stage, a woman has a 95% chance of being cured. Unfortunately, only 25% of cases are found at Stage I.
- Stage II: Cancer is in one or both ovaries and has spread to other part of the pelvis.
- Stage III: Cancer is in one or both ovaries, and has spread to nearby lymph nodes or to other abdominal organs, excluding the liver.
- Stage IV: Cancer is in one or both ovaries, and has spread to the liver or sites outside the abdomen.

Ovarian Cancer: Survival by Stage (FIGO 1994 Data):

Stage	5-year Survival Rate
Ia	83.5
Ib	79.3
Ic	73.1
IIa	64.6
IIb	54.2
IIc	61.3
IIIa	51.7
IIIb	29.2
IIIc	17.7
IV	14.3

The case for early detection:

As can be seen from the 5-year survival rates by stage of ovarian cancer, early detection is desirable. About 80 to 85% of Stage I ovarian cancer patients survive beyond 5 years. Unfortunately, due to the non-specific symptoms, most (approximately 75%) of ovarian cancer patients present with advanced stage disease. The most common symptoms vague and often mimic other common medical problems (such as Irritable Bowel Syndrome).

The American College of Preventative Medicine practice policy states:

“The evidence is insufficient at this time to recommend physical examination, ultrasonography, biochemical markers, or genetic screening for asymptomatic women for early detection of ovarian malignancy. Results of studies thus far indicate that, even in a high-risk population, many women must undergo surgical procedures to diagnose relatively few cancers.”

Source: Screening Asymptomatic Women for Ovarian Cancer:
American College of Preventive Medicine Practice Policy Statement
Rebecca Ferrini, MD, MPH

Types of Screening:

Pelvic Exam – While an annual pelvic exam is recommended for other conditions for the high risk group, an ovarian

CA 125 – A biochemical marker. Elevated levels have been shown to indicate a higher risk of ovarian cancer. Test has high false-positives and if a result is positive, further testing via Ultra-sound is recommended.

Transvaginal Ultra-sound – Useful as a second stage test.

BRCA1 or BRCA2 (breast cancer 1 or 2) – genetic testing for altered BRCA gene, which would indicate a higher risk for ovarian cancer.

- From the survey results received it is evident that ovarian cancer screening is already included as a benefit to employees and individual health plan members when medically necessary.
- Denied claims for ovarian cancer screening from survey results are not segregated into the types of tests that may be performed. As new research and technology emerges, new ovarian cancer screening techniques will become available. The denied claims could be for genetic testing, specifically for an altered BRCA1 or BRCA2 gene, which is an expensive test (range of cost), false positives generally make the testing for this unfeasible, economically as well as clinically.
- Medically necessary needs to be defined in the Bill. Does medically necessary mean guidelines that a specific doctor deems necessary? Does it mean a Board of doctors (there are Boards, but are they recognized)? Does it mean the health plans definition of Medically necessary – which is how the claims are being adjudicated now.

There are several new studies underway for testing screening methods and developing new screening methods. John Hopkin's ovarian cancer center of excellence states that serial testing using CA-125 is more effective than annual CA-125 testing. Elevated levels of CA-125 alone are not specific enough and only generally give an indication of higher chance of ovarian cancer. Instead they recommend testing the levels several times and looking for sudden changes in the level as being more predictive. The National Cancer Institute has clinical trials for the effectiveness of ovarian screening techniques.

Cost of Screening:

Two approaches were evaluated one using biannual transvaginal ultrasound (assuming 7% of women recalled for abnormal findings and 1.3% false-positive results in diagnostic surgery) and another using annual CA 125 assuming 3% recall and .2% false-positive results)

Annual Outcomes of Ovarian Cancer Screening in a Hypothetical Cohort of 10,000 Women Aged 50 to 64 Assuming 40% Mortality reduction an Annual Incidence of 40 per 100,000.

Screening	CA125	Transvaginal Ultrasound
Number of women participating	10,000	10,000
Screening interval	Annual	Every 2 years
Number of screening tests carried out per year	10,000	5,000
Number of women recalled for further assessment per year who do not have primary ovarian cancer	300 (3% of screens)	350 (7% of screens)
Number of women undergoing surgery per year who do not have Primary ovarian cancer	20 (.2% of screens)	65 (1.3% of screens)
Maximum number of cancers detected by screening per year (if 100% sensitivity)	4	4
Number of additional 5 year survivors per year	1.5	1.5
Predictive value of recall (if 100% sensitivity)	1.3%	1.1%
Predictive value of diagnostic surgery (if 100% sensitivity)	17%	5.8%

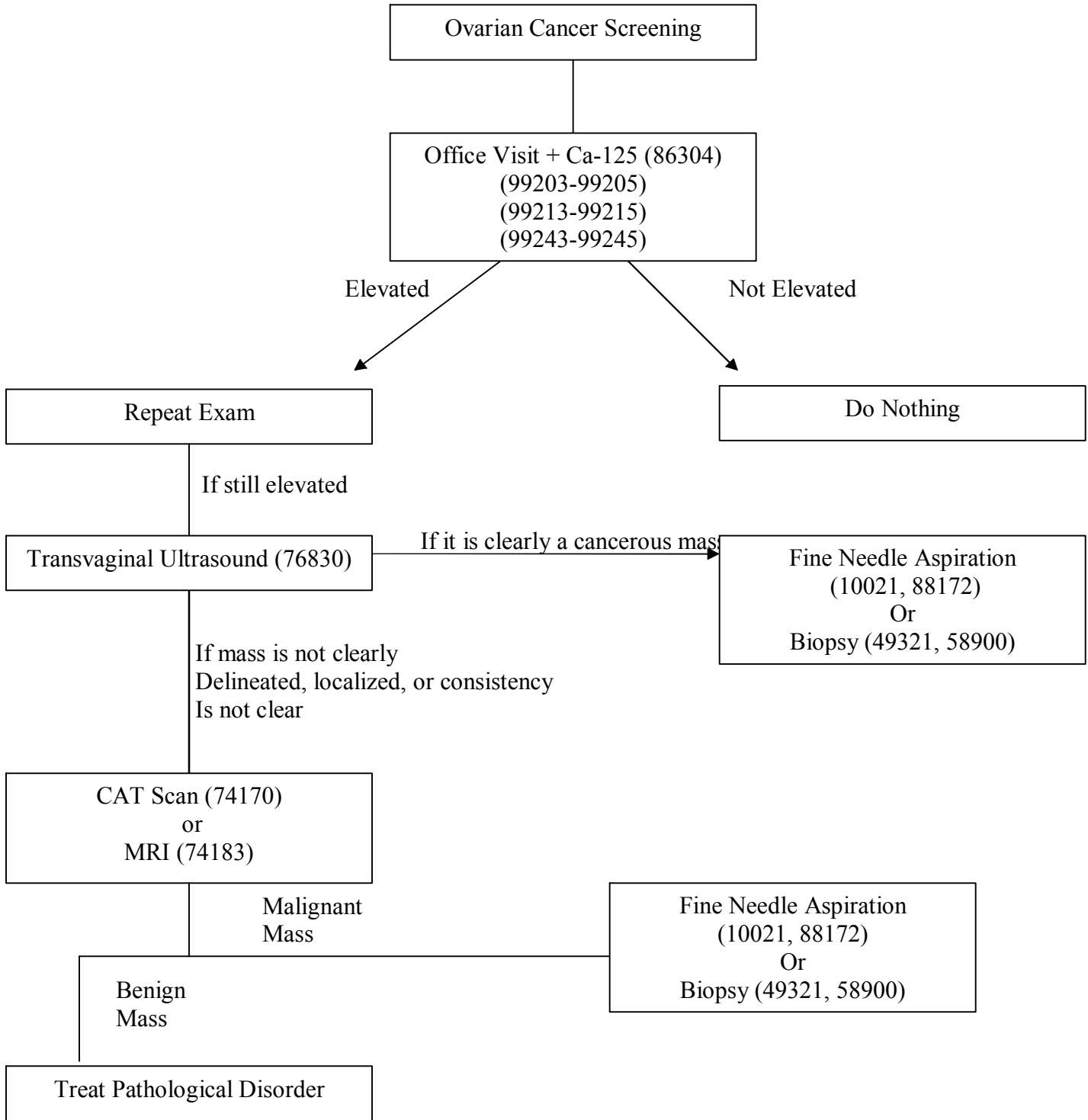
From Screening for Ovarian Cancer: Brief Evidence Update (Heidi Nelson, MD, MPH; Carolyn Westhoff, MD, MPH; Jeffrey Piepert, MD, MPH; Al Berg, MD, MPH)

Marsh Actuarial Consulting

Medicare fee schedule in New Jersey:

Description	Medicare Allowable for New Jersey
Office visit and other outpatient services, established patient; Level 3	\$ 90.47
Immunoassay for tumor antigen, quantitative; CA 125	\$ 139.52
Ultrasound, transvaginal-Doctor's Office	\$ 340.63
Ultrasound, transvaginal-professional component	\$ 167.86
Ultrasound, transvaginal- Facility	\$ 874.83
Fine needle aspiration; without imaging guidance	\$ 239.80
Cytopathology, evaluationof fine needle aspirate; immediate cytohistologic study to determine adequacy of specimen(s)	\$ 195.66
Cytopathology, evaluationof fine needle aspirate; immediate cytohistologic study to determine adequacy of specimen(s)-professional component	\$ 153.15
Laparoscopy, surgical; with biopsy (single or multiple)	\$ 1,676.42
Biopsy of ovary, unilateral or bilateral (sep. proc)	\$ 1,651.90
Computer tomography, abdomen; without contrast material, followed by contrast materal(s) and further sections	\$ 1,532.00
Computer tomography, abdomen; without contrast material, followed by contrast materal(s) and further sections-professional component	\$ 368.97
Magnetic resonance (eg, proton) imaging, abdomen; without contrast material(s), followed by with contrast material(s) and further sequences	\$ 3,700.00
Magnetic resonance (eg, proton) imaging, abdomen; without contrast material(s), followed by with contrast material(s) and further sequences-professional component	\$ 573.89

Procedures involved in Ovarian Cancer Screening:



The cost of screening for ovarian cancer is highly dependent on the population being screened. The Bill requires coverage for “medically necessary expenses incurred in screening for ovarian cancer for symptomatic women or women at risk of ovarian cancer, which coverage shall include, but is not limited to, an annual pelvic examination, an ultrasound and blood testing for cancer markers.”

The following cost analysis assumes the current indicated course of medically necessary treatment as indicated by the sources referenced in this report. The diagram above visually represents the current status of screening for ovarian cancer. New developments will likely continue to emerge which are not considered here.

Development of Cost for Ovarian Cancer Screening

Step 1:

Population to be screened

Women at Risk of ovarian cancer or symptomatic women:

Women at Risk

- Women over 40;
- Women who have never been pregnant;
- Women who are identified with a specific mutation in a gene called BRCA1 or BRCA2 (short for breast cancer 1 and breast cancer 2 respectively);
- Women whose mothers, sisters or daughters have had ovarian cancer; although most affected women do not have a family history of ovarian cancer,
- Women with a history of ovarian, breast, uterine or colon cancer on either side of her family
- Women with a personal history of breast, uterine or colon cancer; and
- Smoking

New Jersey’s incidence of ovarian, breast, uterine and colon cancer are:

Ovarian	12.9 per 100,000
Breast	119.0 per 100,000
Uterine	22.9 per 100,000
Colon	44.9 per 100,000
Total	199.7 per 100,000 or .2%

Source: U.S. Cancer Statistics Working Group. United States Cancer Statistics: 2003 Incidence and Mortality. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; 2006.

Women over 40 – more specific post-menopausal women from age 50 to 65, which represents approximately 10% of the insured population. The average age of onset of ovarian cancer is age 61.

National Institute of Health (National Cancer Institute):

“Family History as a Risk Factor for Breast Cancer: In cross-sectional studies of adult populations, 5% to 10% of women have a mother or sister with breast cancer, and about twice as many have either a first-degree relative or a second-degree relative with breast cancer.”

If we use the high end of the above estimate, then 2 times the 5 to 10% range indicates that 20% of women have either a first-degree or second degree relative with breast cancer. Breast cancer has an annual incidents rate of 119.0 per 100,000 and we are concerned with a combined cancer rate of 199.7 per 100,000. If we strictly take the 20% and increase the percentage for the increase in cancer rate we would have approximately 33% of women with either a first-degree or second degree relative with any of these cancers. This is using the high end of the range and some women will experience more than one type of cancer. Of course, only about 5 to 10% of ovarian cancer is genetic.

Additionally, symptomatic women need to be considered. There are no available statistics on how many women will be symptomatic. In fact, it is estimated that most ovarian cancer is asymptomatic. Symptoms are non-specific and have many other possible causes. For this purpose, the 33% of women aged 50 to 65 will be used as the population that needs screening.

Step 2

Procedures performed:

Assume 10,000 women are screened annually

	Number screened 10,000	Cost of Screening	%Positive
Office Visit with CA-125 (\$90.47 + \$139.52)		\$ 229.99	
Percent Elevated			3%
Second Level Screening (10,000 * .03)	300		
CA-125		\$ 139.52	
Percent still Elevated			95%
Third Level Screening (300 * .95)	285		
Transvaginal Ultrasound (\$340.63 in doctors office)		\$ 340.63	
Percent of Positive Ultrasounds			7%
Fourth Number Screened (285 * .07)	20		

Step 3:

Summary of Costs:

Number of Screenings	Procedure Cost	Total Cost
10,000	\$229.99	\$2,299,900
300	\$139.52	\$41,856
285	\$340.63	\$97,080
20	\$3,700.00	\$74,000
<u>2</u>	<u>\$1,600.00</u>	<u>\$3,200</u>
10,607		2,516,036

Average Cost per Screened Individual (\$2,516,036/10,000) \$251.60

Assumed Total Number of Covered Insureds 100,000
 Assume 10% of Covered Insureds are women age 50 to 65 10%
 Assume 33% of women age 50 to 65 are screen based on risk factors and symptoms 33%
 Population Screened per 100,000 3,300

Annual Cost of Screening per 100,000 Covered Insured \$8.30

Average Annual Premium per Covered Insured \$3,600

Percentage increase in Premium Due to Screening 0.23%

* Source: Average Annual Premium per Covered Insured - New Jersey DOBI (Actuarial Division) 2004 Loss Ratio Report. Percentage of covered insured women age 50 to 65, New Jersey Department of Insurance and Banking.

** Covered Insured includes contract holders and their dependents

As seen above, it is estimated that premiums would increase on average .23% with the inclusion of ovarian cancer screening as a mandated benefit. This assumes that ovarian cancer screening is not already covered by carriers.

From the survey information received by carriers, ovarian cancer screening is already covered to some extent by carriers.

The cost analysis above does not include new screening techniques that may be developed. From a review of the medical literature on the topic, new screening techniques are being tested at this time.