**Subject:** Prophylactic Bilateral Oophorectomy

**Policy Number:** NMP340

**Effective Date:** May 2007

**Updated:** August 2015

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This National Medical Policy is subject to the terms in the IMPORTANT NOTICE at the end of this document

**For Medicaid Plans:** Please refer to the appropriate Medicaid Manuals for coverage guidelines prior to applying Health Net Medical Policies

**The Centers for Medicare & Medicaid Services (CMS)**
For Medicare Advantage members please refer to the following for coverage guidelines first:

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<tr>
<th>Use</th>
<th>Source</th>
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<tr>
<td></td>
<td>National Coverage Determination (NCD)</td>
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| Article (Local)* |                      |
| Other |                      |
| None | Use Health Net Policy |

**Instructions**
- Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.
- Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under “Reference/Website” and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region. *Note: Health Net must follow local coverage determinations (LCDs) of Medicare Administration Contractors (MACs) located outside their service area when those MACs have exclusive coverage of an item or service. (CMS Manual Chapter 4 Section 90.2)*
- If more than one source is checked, you need to access all sources as, on occasion, an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.
• If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

**Current Policy Statement**

Health Net, Inc. considers prophylactic bilateral oophorectomy medically necessary for specific women with high risk factors for ovarian cancer, if they meet any of the following criteria:

1. Women with breast and ovarian susceptibility genes (BRCA1 or BRCA2) mutations confirmed by genetic testing (Genetic screening is medically necessary for women who meet the criteria as outlined in the Health Net Genetic Testing for BRCA1, BRCA2 and Multi-site BRCA3); or

2. Women with a personal history of breast cancer and at least one first degree relative (e.g., mother, sister, daughter) with history of ovarian cancer; or

3. Women with one or more second degree relatives (e.g., maternal or paternal aunt, grandmother, niece) with ovarian cancer; or

4. Women who have two first degree relatives (e.g., mother, sister, daughter) with a history of ovarian and/or breast cancer; or

5. Women who are beyond childbearing age who have been diagnosed with a hereditary ovarian cancer syndrome (e.g., Lynch syndrome) based on a family pedigree constructed by a genetic counselor or physician competent in determining the presence of an autosomal dominant inheritance pattern.

Note: The above criteria are based on recommendations from the National Cancer Society, the National Cancer Institute, the U.S. Preventive Services Task Force (USPSTF), and the American College of Obstetricians and Gynecologists (ACOG)

**Hysterectomy with Prophylactic Oophorectomy**

Health Net, Inc. considers prophylactic hysterectomy medically necessary when performed in conjunction with prophylactic bilateral oophorectomy when any of the following criteria are met:

- Lynch syndrome II mutation
- Women who meet criteria for a prophylactic oophorectomy and who, after risk/benefit discussion with their physician, choose to have prophylactic hysterectomy in conjunction with oophorectomy

Note: The above criteria are consistent with recommendations from the National Cancer Institute and the National Institute of Health consensus.

**Not Medically Necessary**

Health Net Inc. considers a unilateral oophorectomy at the time of hysterectomy when both ovaries are in place not medically necessary. Per ACOG’s current guidelines, removal of one ovary at the time of hysterectomy in pre-menopausal women may indicate the suspicion of clinical disease. The likelihood of future pathology in the retained ovary is therefore greater. The patient should be counseled before surgery that if ovarian pathology is found, bilateral oophorectomy may be indicated.
(September 2005) The U.S. Preventive Services Task Force (USPSTF) recommends against routine referral for genetic counseling or routine breast cancer susceptibility gene (BRCA) testing for women whose family history is not associated with an increased risk for deleterious mutations in breast cancer susceptibility gene 1 (BRCA1) or breast cancer susceptibility gene 2 (BRCA2).

**Codes Related To This Policy**

**NOTE:**
The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all inclusive.

On October 1, 2015, the ICD-9 code sets used to report medical diagnoses and inpatient procedures will be replaced by ICD-10 code sets. Health Net National Medical Policies will now include the preliminary ICD-10 codes in preparation for this transition. Please note that these may not be the final versions of the codes and that will not be accepted for billing or payment purposes until the October 1, 2015 implementation date.

**ICD-9 Codes**

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<th>Code</th>
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<tr>
<td>V10.3</td>
<td>Personal history of malignant neoplasm, breast</td>
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<tr>
<td>V16.0</td>
<td>Family history of malignant neoplasm, gastrointestinal tract</td>
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<tr>
<td>V16.3</td>
<td>Family history of malignant neoplasm, breast</td>
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<tr>
<td>V16.41</td>
<td>Family history of malignant neoplasm, ovary</td>
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**ICD-10 Codes**

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<td>Z85.3</td>
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<tr>
<td>Z80.0</td>
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**CPT Codes**

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<tr>
<td>58150</td>
<td>Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)</td>
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<tr>
<td>58180</td>
<td>Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)</td>
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<td>58262</td>
<td>Vaginal hysterectomy for uterus 250 grams or less; with removal of tube(s), and/or ovary(s)</td>
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<td>58291</td>
<td>Vaginal hysterectomy for uterus greater than 250 grams; with removal of tubes(s)), and/or ovary(s)</td>
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<td>58552</td>
<td>Laparoscopy surgical, with vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s), and/or ovary(s)</td>
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<tr>
<td>58554</td>
<td>Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s), and/or ovary(s)</td>
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<td>58661</td>
<td>Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)</td>
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<td>58940</td>
<td>Oophorectomy, partial or total, unilateral or bilateral</td>
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<td>81211</td>
<td>BRCA1, BRCA2 (breast cancer 1 and 2), (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common</td>
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duplication/deletion variants in BRCA1 (ie, exon 13 del3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)

81212 BRCA1, BRCA2 (breast cancer 1 and 2, (eg, hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants

81213 BRCA1, BRCA2 (breast cancer 1 and 2, (eg, hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants

81214 BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants (ie, exon 13 del3.835kb, exon 13 dup6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)

81215 BRCA1 (breast cancer 1) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant

81216 BRCA2 (breast cancer 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis

81217 BRCA2 (breast cancer 2) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant

HCPCS Codes
S3820 Complete BRCA1 and BRCA2 analysis for susceptibility to breast and ovarian cancer (code deleted 12/12)
S3822 Single-mutation analysis (in individual with a known BRCA1 or BRCA2 mutation in the family) for susceptibility to breast and ovarian cancer (code deleted 12/12)
S3823 Three-mutation BRCA1 and BRCA2 analysis for susceptibility to breast and ovarian cancer in Ashkenazi individuals (code deleted 12/12)

Scientific Rationale – Update August 2015
ACOG practice Bulletin on Lynch Syndrome (Nov 2014) recommends, “Prophylactic hysterectomy and bilateral salpingo-oophorectomy is a risk-reducing option for women with Lynch syndrome who have completed childbearing. In general, risk-reducing hysterectomy and salpingo-oophorectomy should be discussed with the patient by their early to mid-40s.”

Scientific Rationale – Update August 2014
Finch et al (2014) sought to estimate the reduction in risk of ovarian, fallopian tube, or peritoneal cancer in women with a BRCA1 or BRCA2 mutation after oophorectomy, by age of oophorectomy; to estimate the impact of prophylactic oophorectomy on all-cause mortality; and to estimate 5-year survival associated with clinically detected ovarian, occult, and peritoneal cancers diagnosed in the cohort. Women with a BRCA1 or BRCA2 mutation were identified from an international registry; 5,783 women completed a baseline questionnaire and ≥ one follow-up questionnaires. Women were observed until either diagnosis of ovarian, fallopian tube, or peritoneal cancer, death, or date of most recent follow-up. Hazard ratios (HRs) for cancer incidence and all-cause mortality associated with oophorectomy were evaluated using time-dependent survival analyses. After an average follow-up period of 5.6 years, 186 women developed either ovarian (n = 132), fallopian (n = 22), or peritoneal (n = 32) cancer, of whom 68 have died. HR for ovarian, fallopian, or peritoneal cancer associated with bilateral oophorectomy was 0.20 (95% CI, 0.13 to 0.30; P < .001). Among women who had no history of cancer at baseline, HR for all-cause mortality to age 70 years associated with an oophorectomy was 0.23 (95% CI, 0.13 to 0.39; P < .001). Investigators concluded preventive oophorectomy was associated with an 80% reduction in the risk of ovarian, fallopian tube, or peritoneal cancer in BRCA1 or BRCA2 carriers and a 77% reduction in all-cause mortality.
Obermair used data from a population-base data linkage study of all women diagnosed with primary breast cancer in Queensland, Australia between 1997 and 2008 (n = 21,067). Rhe authors fitted flexible parametric breast cancer-specific and overall survival models with 95% confidence intervals (also known as Royston-Parmar models) to assess the impact of risk-reducing surgery (removal of uterus, one or both ovaries). They also stratified analyses by age 20-49 and 50-79 years, respectively. Overall, 1,426 women (7%) underwent risk-reducing surgery (13% of premenopausal women and 3% of postmenopausal women). No women who had risk-reducing surgery compared to 171 who did not have risk-reducing surgery developed a gynaecological cancer. Overall, 3,165 (15%) women died, including 2,195 (10%) from breast cancer. Hysterectomy plus BSO was associated with significantly reduced risk of death overall [adjusted hazard ration (HR), 0.69; 95% confidence interval (CI), 0.53-0.89; p = 0.005]. Risk reduction was greater among premenopausal women, whose risk of death halved (HR, 0.45; 95% CI, 0.25-0.79; p < 0.006). This was largely driven by reduction in breast cancer-specific mortality (HR, 0.43; 95% CI, 0.24-0.79; p < 0.006). The authors concluded the population-based study found that risk-reducing surgery halved the mortality risk for premenopausal breast cancer patients. Replication of our results in independent cohorts and subsequently randomized trials are needed to confirm these findings.

**Scientific Rationale – Update August 2013**

Per the National Comprehensive Care Network (NCCN) guidelines on Genetic/Familial High-Risk Assessment: Breast and Ovarian Cancer (version 3.3013)"

“Women with BRCA 1/2 mutation are at increased risk for both breast and ovarian cancers (including fallopian tube cancer and primary peritoneal cancer). Although the risk of ovarian cancer is generally considered to be lower than the risk of breast cancers in BRCA 1/2 mutation carrier, the absence of reliable methods of early detection and the poor prognosis associated with advanced ovarian cancer have lent support for the performance of bilateral risk reduction salpingo-oophorectomy (RRSO) after completion of childbearing in these women.” The NCCN noted that the effectiveness of RRSO in reducing the risk of ovarian cancer in carriers of BRCA 1/2 mutation has been demonstrated in a number of studies. NCCN reports that in a report of a meta-analysis of 10 studies of BRCA 1/2 mutation carriers showed approximately 80% reduction in the risk of ovarian or fallopian cancer following RRSO.

Per NCCN, RRSO is also reported to reduce the risk of breast cancer in carriers of BRCA 1/2 mutation by approximately 50%. The NCCN reported the reduction in breast cancer risk for carriers of BRCA 1/2 mutation undergoing RRSO may be associated with decreased hormonal exposure following surgical removal of the ovaries. Greater reductions in breast cancer risk were observed in women with a BRCA 1 mutation who had a RRSO at age 40 or younger relative to BRCA 1 carriers aged 41-50 years who had the procedure. A nonsignificant reduction in breast cancer risk was found in women aged 51 or older although only a small number of women were included in this group. NCCN notes the optimal age for RRSO is difficult to specify.

The NCCN panel recommends RRSO for women with a known BRCA 1/2 mutation, ideally between ages 35-40 years and upon completion of childbearing or at an individualized age based on earliest age of ovarian cancer diagnosed in the family.

Singh et al (2013) reported that despite substantial survival benefits of risk-reducing mastectomy (RRM) and risk-reducing bilateral salpingo-oophorectomy (RRBSO) among BRCA mutation carriers, only a minority elect to undergo these procedures. They investigated factors that might influence decision making regarding prophylactic surgeries
among women with BRCA mutations. Unaffected BRCA mutation carriers who were counseled at a single center and either underwent prophylactic surgery or participated in a high-risk surveillance program at the institution from 1998 through 2010 were included in the study. Medical records were reviewed and data collected included age, family history, parity, mutation type, history of breast biopsy or cosmetic surgery, and uptake of prophylactic surgeries. Among 136 unaffected women with BRCA mutations, uptake of RRM was 42% and uptake of RRBSO was 52%. Family history of first- and second-degree relatives being deceased from breast cancer was predictive of uptake of RRM and of RRBSO and history of a mother lost to pelvic cancer was predictive of uptake of RRBSO. Parity also predicted both RRM and RRBSO uptake. Age at the time of genetic testing and history of breast biopsy or cosmetic surgery were not predictive of RRM uptake. Investigators concluded perceptions of cancer risk are heavily influenced by particular features of an individual’s family history and may be motivators in preventive surgery more than actual cancer risk estimations themselves. Awareness of subtle factors beyond the statistical risk for cancers is relevant when counseling at-risk women.

Mannis et al (2013) surveyed a large cohort of women after BRCA testing to identify the prevalence and posttest predictors of risk-reducing and screening interventions. A median of 3.7 years after BRCA testing, 1447 women who received genetic counseling and BRCA testing at 2 hospital sites were surveyed, with a 77.6% response rate. The authors analyzed data from 1077 survey respondents. They performed univariate and multivariate logistic regression analyses to identify predictors of risk-reducing salpingo-oophorectomy (RRSO), screening transvaginal ultrasonography (TVUS), and screening serum cancer antigen 125 (CA-125). Among the respondents, 201 women (18.7%) received positive test results for a deleterious mutation, 103 women (9.6%) received true-negative results, and 773 women (71.8%) received uninformative results. Overall, 19.1% of eligible women underwent RRSO and 39.6% used screening procedures. A positive BRCA result predicted RRSO, TVUS, and serum CA-125. Similarly, a true-negative BRCA result reduced the OR for RRSO, TVUS, and serum CA-125. Of the 71.8% of women who received uninformative results after BRCA testing, 12.3% subsequently underwent RRSO, 33.8% reported ever having undergone screening serum CA-125 since BRCA testing, and 37.3% reported ever having undergone screening TVUS since BRCA testing. Authors concluded results of BRCA testing strongly predict RRSO and ovarian cancer screening. Use of RRSO and ovarian screening was reported in a sizable percentage of non-BRCA carriers despite insufficient data to determine the effectiveness of these interventions.

**Scientific Rationale – Update September 2011**
The National Comprehensive Care Network 2011 guidelines on hereditary breast and /or ovarian cancer syndrome (2011), recommend risk-reducing salpingo-oophorectomy for women with a known BRCA1/2 mutation, ideally between 35 and 40 years of age, and on completion of child bearing or individualized based on earliest age of onset of ovarian cancer in the family. Counseling includes a discussion of reproductive desires, extent of cancer risk, degree of protection for breast and ovarian cancer, management of menopausal symptoms, possible short term hormone replacement therapy to a recommended maximum age of natural menopause, and related medical issues.

**Scientific Rationale – Update December 2010**
According to the American College of Obstetricians and Gynecologists (ACOG), the most effective method of preventing ovarian cancer is surgical removal of the ovaries and fallopian tubes. Recognizing women with a genetically increased risk of ovarian cancer may provide the opportunity of preventing most hereditary ovarian carcinomas. Inherited susceptibility to ovarian cancer has the greatest impact of all ovarian cancer risk factors. Women with the highest risk of ovarian carcinoma are those with hereditary breast and
Prophylactic bilateral oophorectomy is the preventive, surgical removal of the ovaries. The goal of this procedure is to prevent the development of ovarian cancer and/or reduce the risk of breast cancer in women who are at high risk for these diseases.

The National Institutes of Health (NIH) Consensus Statement on Ovarian Cancer recommends that women at inherited risk of ovarian cancer undergo prophylactic oophorectomy after completion of childbearing.

Per the U.S. Preventive Services Task Force (USPSTF) there is fair evidence that prophylactic oophorectomy significantly decreases breast and ovarian cancer incidence, for women at high genetic risk. (September 2005)

The American College of Obstetricians and Gynecologists (ACOG) have the following recommendations based primarily on consensus and expert opinion:

- The decision to perform prophylactic oophorectomy should not be based only on age; it should be a highly individualized decision that takes into account several patient factors and choices.
- Removal of one ovary at the time of hysterectomy in pre-menopausal women may indicate the suspicion of clinical disease. The likelihood of future pathology in the retained ovary is therefore greater. The patient should be counseled before surgery that if ovarian pathology is found, bilateral oophorectomy may be indicated.
- Hormone replacement therapy should be considered for women undergoing prophylactic oophorectomy, and patients should be counseled about the risks and benefits of hormone replacement therapy prior to undergoing surgery.
- Compliance with hormone replacement therapy is important in women undergoing prophylactic oophorectomy to reduce the risk of future morbidity.
- Prophylactic oophorectomy should be considered for select women at high risk of inherited ovarian cancer.
• In addition to health risks and benefits, patient counseling should include consideration of how oophorectomy may relate to the individual patient's body image, perceptions concerning sexuality, and personal feelings.

The National Clearinghouse Guidelines, which are a source of evidence based medicine, mirror the recommendations of ACOG.

The lifetime probability of ovarian cancer increases from about 1.7% (17 out of 1,000) in a 35-year-old woman without a family history of ovarian cancer compared with 16 to 60% (160–600 out of 1,000) of women with altered BRCA1 or BRCA2 genes. Three to nine percent of these patients may have ‘hereditary ovarian cancer syndromes’.

The term ‘hereditary ovarian cancer syndrome’ refers to the following three types of cancer scenarios:

• **Breast-ovarian cancer syndrome**
  → This occurs in families with clusters of women with ovarian cancer and/or breast cancer, due to mutations in the tumor suppressor genes BRCA1 and BRCA2.

  → Certain ethnic groups, such as Ashkenazi Jews, have high rates of specific mutations of these genes. The large number of mutations described makes genetic testing and patient counseling complex, and illustrates the need for genetic counseling by a qualified health care provider.

• **Site-specific ovarian cancer syndrome**
  → This occurs in families with clusters of ovarian cancer and in most cases this syndrome is linked to mutations in the BRCA1 gene.

• **Lynch syndrome I** (Hereditary Non-Polyposis Colorectal Cancer) (HNPCC)
  → This is characterized by an inherited predisposition to the development of the early onset (usually pre-menopausal) of adenocarcinomas of the colon with proximal colonic predominance. The lifetime risk of colorectal cancer is 80%.

• **Lynch syndrome II**
  → There is also a genetic predisposition to cancer of the ovary, pancreas, breast, bile duct, cervix, endometrium, and of the urologic (most commonly ureter and renal pelvis) and gastrointestinal systems. (The risk of endometrial cancer associated with HNPCC is approximately 40%, while the risk of ovarian cancer is 10%).

Kramer et al (2005) completed a study to evaluate if patients post-oophorectomy had decreased rates of breast cancer. Females from multiple-case breast/ovarian cancer families with BRCA1 mutations were observed prospectively for breast cancer incidence. 33 cases of breast cancer developed in 98 women with BRCA1 mutations during follow-up, yielding an estimated cumulative lifetime breast cancer risk of 80%. Six of the 33 mutation-positive women who underwent oophorectomy during follow-up developed breast cancer, compared with 27 of 65 mutation carriers with intact ovaries. Estimates of breast cancer risk demonstrated that the protective effect of oophorectomy was strongest among women...
who were pre-menopausal at the time of surgery. When surgical status was ignored, the strong protective effect of oophorectomy, coupled with the high prevalence of the procedure in these families, led to a significantly lower estimate of the breast cancer in BRCA1 mutation carriers. In summary, differing rates of oophorectomy likely represent an underappreciated basis for a portion in estimated breast cancer described in BRCA mutation carriers, particularly mutation carriers from extensively affected, multiple-case families.

Weber et al (2000) evaluated the effectiveness of ovary removal in lowering risk of ovarian cancer. They compared 248 BRCA1 or BRCA2 mutation carriers post oophorectomy, to 245 BRCA positive women, who decided against surgery. The patients were followed for an average of 9.8 years to track their cancer status. There was a 98 percent reduction in their risk for developing ovarian cancer after ovariectomy. The risk did not fall to zero because the tissue lining the abdominal cavity cannot be removed and on rare occasions can develop into "ovarian-like" cancers called primary peritoneal carcinomas. In addition, the risk for breast cancer in the group that chose surgery was reduced by 46 percent.

**BRCA Testing**

Genetic screening is appropriate for women who meet criteria for genetic screening as outlined in the Health Net Genetic BRCA Testing policy. Inherited alterations in the genes called BRCA1 and BRCA2 (short for BReast CAncer 1 and BReast CAncer 2) are involved in many cases of hereditary breast and ovarian cancer. If that person is found to have an altered BRCA gene, the specific change is referred to as a "known mutation". Prophylactic bilateral oophorectomy protects against breast cancer in these women.

Mutations to the BRCA1 (breast cancer 1, early onset) gene, also increases the risk of ovarian, fallopian tube, prostate and colon cancers. For women with BRCA1 mutations, the risk of ovarian cancer begins to rise after the childbearing ages. The prophylactic oophorectomy should be offered to these women at this time, and only deferred beyond this time, following a careful discussion of the risks and benefits.

The BRCA2 gene is different from the BRCA1 gene, but their functions appear to be similar. The proteins made by both genes are essential for repairing damaged DNA. Mutations of the BRCA gene are thought to interfere with the DNA repair function of the normal gene, resulting in the accumulation of chromosomal abnormalities and a propensity to develop malignancy. Researchers have identified about 450 mutations in the BRCA gene, many of which cause an increased risk of cancer. Certain variations of the BRCA2 gene cause an increased risk for breast cancer, as well as an increased risk of prostate, and pancreatic cancers. In particular, mutations in the central part of the gene have been associated with a higher risk of ovarian cancer.

For women with BRCA2 mutations, the ovarian cancer risk does not begin to rise until about 10 years later than those with BRCA1 mutations, during the pre-menopausal time. It is important to remember that the deferral of prophylactic oophorectomy until the time of natural menopause may cause the loss of substantial protection against breast cancer that oophorectomy affords. Occult ovarian cancers have been detected in 2-10% of surgical specimens from BRCA mutation carriers undergoing risk-reducing oophorectomies.

The U.S. Preventive Services Task Force (USPSTF) recommends that women whose family history is associated with an increased risk for deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing. (September 2005)

The Journal of the National Cancer Institute (1999; 91(17) sites an article on 'Preventing Breast Cancer in Women with BRCA1 Mutations’. The study consisted of 43 BRCA1 positive
women who were post-op prophylactic oophorectomy, in addition to 79 control subjects (BRCA1 mutation carriers), who had not undergone ovarian surgery. The women had been followed for an average of 9.6 years post-op, or 8.1 years (controls). Other than their prophylactic surgery, the control and subject groups were well balanced for a variety of clinical factors, such as age and parity. The findings of the control group, as well as findings from the general population, suggests that for women with BRCA1 mutations, prophylactic ovarian surgery may reduce the risk of breast and ovarian cancer. Presumably, the decreased breast cancer benefit arises from reduction in estrogen exposure.

**Prophylactic oophorectomy at hysterectomy**

Approximately 600,000 hysterectomies are performed each year in the United States and between 50 to 60 percent of those procedures involve oophorectomy. Prophylactic bilateral oophorectomies are often performed concomitantly with hysterectomies in women, after the childbearing years. Despite ovarian ultrasound, the CA 125 antigen test, and other tumor marker and genetic tests in development, nothing has proven to be sensitive or specific enough to detect the early presence of ovarian cancer. Therefore, despite this testing that is available, 70 percent of the patients are not diagnosed until after the cancer has spread beyond the ovary.

Ovarian cancer is the fourth most common cause of cancer death and the most common cause of gynecologic cancer death in women with an estimated 23,300 new diagnoses and 13,900 deaths related to ovarian cancer each year. Oophorectomies do not eliminate the risk of ovarian cancer (women can develop peritoneal carcinoma, which acts like ovarian cancer), however, reported cases are rare.

The mean age of menopause in the United States is approximately 51 years; only 3.8 percent of women who are ovulatory at age 40 become menopausal by age 45. Therefore, the positive effects of several years of physiologic estrogen production and the issues related to hormone replacement therapy (HRT) should be carefully considered before prophylactically removing the ovaries of premenopausal women at hysterectomy. Others have shown that women who undergo surgical menopause appear to have more risk factors for cardiovascular disease that may account for the increase in risk with this procedure.

The Cancer Genetics Studies Consortium concluded that, although minimal data were available on the efficacy of hysterectomy combined with oophorectomy in the management of HNPCC, the two surgeries should be offered as a combined option for preventing endometrial and ovarian cancer in women known to have HNPCC or to be carriers of HNPCC-associated mutations. The optimal age for this procedure is not established, but is likely to be pre-menopausal and after the child bearing ages, given the early onset of endometrial cancer among female HNPCC-associated mutations carriers.

Advantages of prophylactic oophorectomy at the time of hysterectomy include all of the following:

- Reduction in risk of developing ovarian cancer — Prophylactic oophorectomy reduces, but does not eliminate, the risk of developing ovarian cancer because these women remain at risk for developing ovarian-like cancers in the peritoneum, known as papillary serous carcinoma of the peritoneum (PSCP). The fallopian tubes should also be removed in these cases.

- Avoidance of reoperation for ovarian pathology — Reoperation for ovarian pathology, termed residual ovary syndrome (ROS), becomes necessary in 3 to 4 percent of
women who retain one or both ovaries. The majority of these surgeries are performed because of pelvic pain or a pelvic mass within five years of the hysterectomy. In one series of 73 women with ROS, histological examination revealed functional cysts, benign neoplasms, and ovarian carcinoma in 51, 43, and 12 percent of cases, respectively (some patients had more than one diagnosis). In addition, ROS was more common in women who underwent hysterectomy at a young age, possibly because of the longer period of postprocedure ovarian function with a greater opportunity for functional ovarian pathology.

→ Relief of symptoms related to continued ovarian function — Relief of symptoms related to continued ovarian function can be an advantage for some women, such as those with cyclic migraine or epilepsy or premenstrual syndrome.

Disadvantages of prophylactic oophorectomy at the time of hysterectomy include all of the following:

→ The primary disadvantage of oophorectomy is loss of natural ovarian hormone secretion resulting in a need for hormone therapy to relieve the clinical manifestations of surgical castration (eg, hot flashes).

→ Other possible disadvantages include changes in self image and decreased libido, which is attributed to loss of ovarian testosterone production. In premenopausal women, the mean reductions in serum testosterone and estradiol concentration are 50 and 80 percent, respectively. However, at least one study has shown that sexuality was unaltered after oophorectomy, despite lower concentrations of ovarian sex steroids.

→ In addition, epidemiological studies have suggested that premature menopause (natural or surgical) is associated with an increased risk of atherosclerosis; however, women who undergo surgical menopause appear to have other risk factors for cardiovascular disease, which may account for the increase in risk.

Schmeler et al. (2006) conducted a retrospective study (n=315) to determine the reduction in the risk of gynecologic cancers associated with prophylactic hysterectomy and bilateral salpingo-oophorectomy in women with the Lynch syndrome. Women who had undergone prophylactic hysterectomy (n=61) and those who had undergone prophylactic hysterectomy and bilateral salpingo-oophorectomy (n=47) were matched with mutation-positive women who had not undergone prophylactic procedures (n=210). Endometrial cancer was diagnosed in 69 women in the control group (33%), and ovarian cancer was diagnosed in 12 women in the control group (5%). It was noted that no diagnosis of primary peritoneal cancer after prophylactic bilateral salpingo-oophorectomy was found; however sample size and limited follow-up time may have impacted this finding. According to the authors, study “findings suggest that prophylactic hysterectomy with bilateral salpingo-oophorectomy is an effective strategy for preventing endometrial and ovarian cancer in women with the Lynch syndrome.”

Despite the lack of randomized controlled trials (RCT), the published peer-reviewed medical literature indicates that prophylactic oophorectomy should be considered for premenopausal, high-risk women (i.e., women known to carry the BRCA1 and/or BRCA2 mutation or to have a lineage of familial cancer), and only after completion of childbearing.
In addition, medical literature suggests that a prophylactic hysterectomy should be performed in conjunction with oophorectomy in women from families with Lynch Syndrome.

It is imperative that women undergoing prophylactic oophorectomy with or without hysterectomy understand that this surgery does not completely eliminate the risk of developing cancer. Counseling regarding the risks and benefits of the procedure is equally important for women considering this preventive measure. However, according to studies that have been done, there is a very high reduction in ovarian and breast cancer in patients who have had a prophylactic oophorectomy. More randomized, long term follow up studies are necessary, since many of the studies are fairly new, but the results are encouraging.

**Medical Advisory Council**

- May 2007: Medical Advisory Council Initial Draft
- December 2010: Update – no revisions
- September 2011: Update – no revisions
- August 2014: Update – no revisions
- August 2015: Update – no revisions

**This policy is based on the following evidence-based guidelines:**

Prophylactic Bilateral Oophorectomy Aug 15


References – Update August 2015


References – Update August 2014


References – Update August 2013


References – Update August 2012


References – Update September 2011


References – Update December 2010


References
19. Dowdy SC, Stefanek M, Hartmann LC. Surgical risk reduction,

Important Notice

General Purpose.
Health Net’s National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net’s National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member's benefits contract as described this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to practice medicine.

Policy Effective Date and Defined Terms.
The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.
Policy Amendment without Notice.
Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

No Medical Advice.
The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

No Authorization or Guarantee of Coverage.
The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

Policy Limitation: Member’s Contract Controls Coverage Determinations.
Statutory Notice to Members: The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member’s contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member’s contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member’s contract shall govern. The Policies do not replace or amend the Member’s contract.

Policy Limitation: Legal and Regulatory Mandates and Requirements
The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

Reconstructive Surgery
CA Health and Safety Code 1367.63 requires health care service plans to cover reconstructive surgery. “Reconstructive surgery” means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

(1) To improve function or
(2) To create a normal appearance, to the extent possible.

Reconstructive surgery does not mean “cosmetic surgery,” which is surgery performed to alter or reshape normal structures of the body in order to improve appearance.

Requests for reconstructive surgery may be denied, if the proposed procedure offers only a minimal improvement in the appearance of the enrollee, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery.

Reconstructive Surgery after Mastectomy
California Health and Safety Code 1367.6 requires treatment for breast cancer to cover prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the co-payment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits. "Mastectomy" means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

Policy Limitations: Medicare and Medicaid
Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.