



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Prophylactic Oophorectomy or Salpingo-oophorectomy With or Without Hysterectomy

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Coverage Policy

CIGNA covers prophylactic oophorectomy or salpingo-oophorectomy as medically necessary when ANY of the following criteria is met:

- genetic mutation confirmed by molecular testing for breast and ovarian cancer susceptibility genes (BRCA1 or BRCA2)
- personal premenopausal history of steroid hormone receptor-positive breast cancer
- personal history of breast cancer and **one** first-degree* relative with a history of ovarian cancer
- two or more first-degree* relatives with early onset ovarian and/or breast cancer
- family history of colon cancer in first- and/or second-degree* relatives
- known familial cancer syndrome associated with increased risk of ovarian cancer (e.g., hereditary nonpolyposis colorectal cancer [HNPCC])

*A first-degree relative is defined as a blood relative with whom an individual shares approximately 50% of his/her genes, including the individual's parents, full siblings, and children.

*A second-degree relative is defined as a blood relative with whom an individual shares approximately 25% of his/her genes, including the individual's grandparents, grandchildren, aunts, uncles, nephews, nieces and half siblings.

CIGNA covers prophylactic hysterectomy as medically necessary when performed with bilateral oophorectomy for those who have been diagnosed with HNPCC, found to be carriers of HNPCC-associated mutations, or are members of HNPCC families as determined by a pattern of occurrence of HNPCC-related cancers.

General Background

Ovarian cancer is the fifth leading cause of cancer death among women in the United States and has the highest mortality rate of all gynecologic cancers. Ovarian and breast cancer are components of several inherited cancer syndromes including familial site-specific ovarian cancer; hereditary breast/ovarian cancer; and Lynch syndrome, which is a combination of breast, ovarian, endometrial, gastrointestinal, and genitourinary cancers. Most hereditary breast and ovarian cancer are caused by inherited mutations in the BRCA1 or BRCA2 genes, which lead to lifetime risks of ovarian cancer of 20–50%. Suggestive family histories of hereditary cancer risk include cancer occurring at young ages; cancer in first-degree relatives; cancer in multiple generations; bilateral, metachronous, or synchronous cancer in one individual; and clustering of cancer on one side of the family (American College of Obstetricians and Gynecologists [ACOG], 2008). Statistically, having an affected first-degree relative approximately doubles a woman's lifetime cancer risk; additional affected first- or second-degree relatives further increase the risk. Women with a family history of cancer of the breast, uterus, colon, or rectum may also have an increased risk of ovarian cancer (National Cancer Institute [NCI], 2006).

Clinical examination (i.e., bimanual pelvic examination) lacks the sensitivity needed to reliably identify early ovarian cancer, and there continues to be a lack of effective ovarian cancer detection methods. Prophylactic oophorectomy, the surgical removal of the ovaries, is a surgical option to reduce the risk of developing both ovarian and breast cancer in high-risk women (e.g., those with BRCA mutations, site-specific ovarian cancer syndrome, or Lynch Syndrome). Although not technically the same, the term risk-reducing salpingo-oophorectomy (RRSO), which includes removal of the ovaries and fallopian tubes, is used interchangeably with prophylactic oophorectomy. RRSO has been shown to reduce the risk of ovarian of ovarian cancer, fallopian tube cancer, and peritoneal cancer by approximately 85–90% in women with known mutations in BRCA1 or BRCA2. RRSO has been shown to decrease overall mortality in women with a BRCA1 or BRCA2 mutation. The procedure has also been shown to reduce the risk of breast cancer by 40–70%. This protection likely occurs only if patients are premenopausal at the time of risk-reducing salpingo-oophorectomy (American College of Obstetricians and Gynecologists [ACOG], 2009). The degree of risk for ovarian or breast cancer, potential morbidity and mortality of surgery and the risks associated with early menopause should be taken into account when considering prophylactic oophorectomy for high-risk women. Potential adverse effects of bilateral oophorectomy and premature menopause include vasomotor symptoms, cardiovascular disease, and osteoporosis (NCI, 2006).

Literature Review

Numerous studies have found that women at inherited risk of breast and ovarian cancer have a decreased risk of ovarian cancer following prophylactic oophorectomy. The available evidence evaluating the impact of prophylactic oophorectomy on individuals at high risk for ovarian cancer includes systematic reviews, case-control and cohort studies. Studies have primarily evaluated women with inherited mutations in BRCA1 or BRCA2. A systematic review (n=18 studies) by Bermejo-Pérez and colleagues (2007) assessed the effectiveness of preventive intervention strategies (i.e., prophylactic surgery, intensive cancer screening, and chemoprevention) implemented in women carrying mutations in BRCA1 or BRCA2 genes, in terms of reducing breast and gynecological cancer incidence and/or mortality. Although methodological flaws were identified in all the studies examined, overall, study results indicated that compared to surveillance, oophorectomy or salpingo-oophorectomy led to a reduction in breast cancer incidence in carriers of BRCA mutations (Bermejo-Pérez, et al., 2007).

Case-control and cohort studies (n=170–1828) with median follow-up through 25 years have demonstrated that prophylactic oophorectomy is associated with a significant reduction in the risk of both ovarian and breast cancer (Domchek, et al., 2006; Finch, et al.; 2006; Rocca, et al., 2006; Rebbeck, et al., 2002; Kauff, et al., 2002).

Hysterectomy Performed with Prophylactic Oophorectomy

Hereditary nonpolyposis colorectal cancer (HNPCC), also known as Lynch syndrome, is an autosomal-dominant condition caused by mutation of one of several deoxyribonucleic acid (DNA) mismatch repair (MMR) genes. This genetic mutation is estimated to account for 5–6% of colorectal cancer cases. Individuals with an HNPCC gene mutation have an estimated 80% lifetime risk of developing colon or rectal cancer (NCI, 2010b). Genetic testing can identify the majority of individuals with HNPCC before they develop cancer. The characteristics of HNPCC include early onset of colorectal cancer (average age at diagnosis is 45 years) and an increased risk of other cancers, predominantly those of the ovary, uterus, stomach and small bowel. Indications of an HNPCC family include multiple relatives with colon cancers, or a colon and endometrial cancer, and clusters of colorectal and other cancers of the gastrointestinal (e.g., stomach, small intestine, pancreas), urinary or female reproductive system. Ovarian cancer risk is reported to be 3.5 times higher in HNPCC families than in the general population.

Literature Review: There is a paucity of evidence in the form of controlled studies demonstrating the effectiveness of prophylactic surgery in at-risk HNPCC mutation carriers, and it is unlikely that randomized controlled studies will be performed, given the rarity and nature of this condition. A systematic review by Lindor et al. (2006) provided recommendations for the clinical management of those with an inherited predisposition to Lynch syndrome. The authors found fair evidence supporting the efficacy of prophylactic hysterectomy and oophorectomy as an option for women age 35 or older who do not want to preserve fertility (Lindor, et al., 2006).

A retrospective study by Schmeler et al. (2006) compared women who had undergone prophylactic hysterectomy (n=61) and those who had undergone prophylactic hysterectomy and bilateral salpingo-oophorectomy (n=47) to mutation-positive women who had not undergone prophylactic procedures (n=210). No endometrial, ovarian, or primary peritoneal cancers developed among the women who had undergone prophylactic surgery, while in the control group, endometrial and ovarian cancers were diagnosed in 69 (33%), and 12 (5%) women respectively.

Burke et al. (1997) reported conclusions of the Cancer Genetics Studies Consortium. It was stated that although no 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 (Burke, et al., 1997).

Despite the lack of robust evidence, limited studies in addition to recommendations based upon expert opinion support consideration of prophylactic oophorectomy with hysterectomy for the management of HNPCC.

Professional Societies/Organizations

The NCCN guidelines for colorectal cancer screening state that prophylactic total abdominal hysterectomy and bilateral salpingo-oophorectomy (TAH/BSO) should be considered as a risk-reducing option for women with HNPCC (NCCN, 2011b).

The National Comprehensive Cancer Network® (NCCN) guidelines state that RRSO has been reported to reduce the risk of both breast and ovarian cancers. The NCCN panel recommends limiting RRSO to women with a known or strongly suspected BRCA1 or BRCA2 mutation (NCCN, 2010b). RRSO may be considered by women with a family history that includes ovarian cancer, especially in view of the lack of a standard approach to screening. The ideal age to perform the procedure is between the ages of 35 and 40 or upon completion of childbearing (NCCN, 2010a).

The National Cancer Institute (NCI) guidelines on the prevention of ovarian cancer states that The risk of ovarian cancer is increased in women who have inherited certain changes in BRCA1 or BRCA2 genes as well as genes that are linked to HNPCC. A woman who has one first degree relative or two or more relatives with ovarian cancer also has an increased risk of ovarian cancer. Women who have a high risk of ovarian cancer may choose to undergo prophylactic oophorectomy (NCI, 2010c).

According to the ACOG guidelines on Hereditary Breast and Ovarian Cancer (HBOC) Syndrome, risk-reducing salpingo-oophorectomy (RRSO) should be offered to women with BRCA1 or BRCA2 mutations by age 40 or after the conclusion of childbearing (ACOG, 2009). The ACOG guidelines on salpingo-oophorectomy state that for women with HNPCC, the average age of ovarian cancer diagnosis is 42 years and the average age of endometrial cancer diagnosis is 50 years. Therefore, it is reasonable to consider prophylactic surgery in women with HNPCC between ages 35 and 40 if childbearing is no longer desired (ACOG, 2008).

The National Hereditary Cancer Task Force developed Canadian consensus recommendations to address the clinical management of patients at high risk of HBOC and related cancers. The recommendations are based on current practice in high-risk cancer clinics that provide care for individuals with known BRCA1 or BRCA2 mutations and pertain to surveillance options, risk-reduction strategies (e.g., bilateral prophylactic salpingo-oophorectomy [BPSO], prophylactic mastectomy), and the use of exogenous hormones. The guidelines state that BPSO appears to be associated with an 85–95% reduction in the risk of ovarian and fallopian tube cancers in women with known BRCA1 or BRCA2 mutations. If performed in the premenopausal period, this intervention may also reduce the risk of developing breast cancer by 50% or more, even in women taking short-term hormone replacement therapy (HRT) after BPSO. The recommendations pertaining to BPSO include the following (Horsman, et al., 2007):

1. The potential benefits of the procedure as a risk-reduction strategy should be raised with all women at high risk.
2. Women considering BPSO should be counseled about age-specific risks of ovarian and breast cancer and also about dealing with menopausal symptoms. They should be managed by a multidisciplinary team that includes at least a geneticist/genetic counselor and gynecologist.
3. In women facing premature menopause, issues relating to HRT and alternatives should be discussed explicitly before surgical intervention. Ongoing medical care addressing health issues related to premature menopause should be available (e.g., regular bone density measurements and assessment of cardiovascular risk factors).
4. Hysterectomy is not routinely recommended unless there are separate clinical indications. It should be considered if women plan to take HRT after the BPSO or if they are on tamoxifen therapy.
5. The possibility that histologically evident epithelial cancer may be detected as a result of the surgical procedure should be discussed in advance.

The U.S. Preventive Services Task Force (USPSTF) found fair evidence in the published scientific literature that women with certain specific family history patterns have an increased risk for developing breast or ovarian cancer associated with BRCA1 or BRCA2 mutations. Fair evidence was also found to support prophylactic surgery for these women, as it significantly decreases breast and ovarian cancer incidence. The USPSTF recommendation is that women with the following family history patterns be referred for genetic counseling that will allow for informed decision-making about testing and further prophylactic treatment:

- two first-degree relatives with breast cancer, one of whom was diagnosed at age 50 or younger
- a combination of three or more first- or second-degree relatives with breast cancer, regardless of age at diagnosis
- a combination of both breast and ovarian cancer among first- and second-degree relatives
- a first-degree relative with bilateral breast cancer
- a combination of two or more first- or second-degree relatives with ovarian cancer, regardless of age at diagnosis
- a first- or second-degree relative with both breast and ovarian cancer, at any age
- a history of breast cancer in a male relative

For women of Ashkenazi Jewish heritage, an increased risk in family history includes any first-degree relative (or two second-degree relatives on the same side of the family) with breast or ovarian cancer (USPSTF, 2005).

The Scottish Intercollegiate Guidelines Network (SIGN) guideline on the management of women with epithelial ovarian cancer states that women at high risk for ovarian cancer can be offered prophylactic oophorectomy. According to SIGN, family history can be used to define women who are at increased risk. Individuals at high risk are those with a first degree relative (mother, father, sister, brother, daughter or son) affected by cancer within a family that meets one of the following criteria (SIGN, 2003):

- two or more individuals with ovarian cancer, who are first degree relatives of each other
- one individual with ovarian cancer at any age, and one with breast cancer diagnosed under age 50 years, who are first degree relatives of each other*
- one relative with ovarian cancer at any age, and two with breast cancer diagnosed under 60 years, who are connected by first degree relationships*
- known carrier of relevant cancer gene mutations (e.g., BRCA1 or BRCA2)
- untested first degree relative of a predisposing gene carrier
- three or more family members with colon cancer, or two with colon cancer and one with stomach, ovarian, endometrial, urinary tract or small bowel cancer in two generations; one of these cancers must be diagnosed under age 50 years
- an individual with both breast and ovarian cancer

* In these categories a second degree relative may be counted if the transmission is via the paternal line (e.g., a sister and a paternal aunt or a sister and two paternal aunts).

Summary

Despite the lack of randomized controlled trials (RCTs), the published, peer-reviewed medical literature indicates that prophylactic oophorectomy should be considered for premenopausal (age 35 or older), high-risk women (i.e., women known to carry the BRCA1 and/or BRCA2 mutation or to have a lineage of familial cancer). The literature also suggests that a hysterectomy should be performed in conjunction with prophylactic oophorectomy in women from families with hereditary nonpolyposis colorectal cancer (HNPCC). For premenopausal women with early breast cancer, ovarian ablation by oophorectomy is a therapeutic option. It is important 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.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT [®] * Codes	Description
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
58262	Vaginal hysterectomy for uterus 250 grams or less; with removal of tube(s), and/or ovary(s)
58291	Vaginal hysterectomy for uterus greater than 250 grams; with removal of tubes(s)), and/or ovary(s)
58542	Laparoscopy, surgical, supracervical hysterectomy for uterus 250 g or less with removal of tube(s) and/or ovary(s)
58544	Laparoscopy, surgical, supracervical hysterectomy for uterus greater than 250 g with removal of tube(s) and/or ovary(s)
58548	Laparoscopy, surgical, with radical hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph nodes sampling(biopsy) with removal of tube(s) and ovary(s), if performed
58552	Laparoscopy surgical, with vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s), and/or ovary(s)
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s), and/or ovary(s)
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250g or less; with removal of tube(s) and/or ovary(s)

58573	Laparoscopy, surgical, with hysterectomy for uterus greater than 250g, with removal of tube(s) and/or ovary(s)
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral

ICD-9-CM Diagnosis Codes	Description
V10.3	Personal history of malignant neoplasm, breast
V16.0	Family history of malignant neoplasm, gastrointestinal tract
V16.3	Family history of malignant neoplasm, breast
V16.41	Family history of malignant neoplasm, ovary
V50.42	Prophylactic organ removal, ovary
V50.49	Prophylactic organ removal, other
V84.02	Genetic susceptibility to malignant neoplasm of ovary

***Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	2/15/2008	0026	Prophylactic Oophorectomy With or Without Hysterectomy

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