Name of Policy: Prophylactic Oophorectomy

Policy #: 259
Category: Surgery

Latest Review Date: November 2009
Policy Grade: Active Policy but no longer scheduled for regular literature reviews and updates.

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
Prophylactic oophorectomy is the surgical removal of both ovaries to prevent the development of ovarian cancer in women who are at high risk for the disease. For those women at increased risk, prophylactic oophorectomy may be considered after the age of 35 if childbearing is complete. The highest risk appears in women with 2 or more first-degree relatives with ovarian cancer. The most important risk factor for ovarian cancer is a family history of a first degree relative (e.g., mother, daughter or sister) with the disease or presence of a BRCA1 or BRCA2 mutation. Increased screening and surveillance of patients at high risk of ovarian cancer have been unsuccessful in identifying patients early in the course of disease such that treatment results in a higher incidence of cure. Prophylactic oophorectomy has been explored as a possible option.

**Policy:**
**Prophylactic oophorectomy meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the following guidelines are met:

- Personal history of breast cancer, which is estrogen receptor positive and/or progesterone receptor positive, and who are premenopausal; **OR**
- BRCA1 or BRCA2 mutation; **OR**
- Two or more first-degree relatives (mother, sister, daughter) **OR** one first-degree relative and one or more second-degree relatives (maternal or paternal grandmother, aunt or niece) with a history of ovarian cancer; **OR**
- Strong family history of colon cancer in first-and/or second degree relatives; **OR**
- Known familial cancer syndrome associated with increased risk of ovarian cancer (e.g., Lynch syndrome)

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

**Key Points:**
According to the National Cancer Institute, the estimated number of new cases of ovarian cancer for 2005 is over 22,000 and deaths from ovarian cancer exceed 16,000. Several cancers arise from the ovary. Epithelial carcinoma of the ovary is one of the most common gynecologic malignancies and the fifth most frequent cause of cancer death in women with 50% of all cases occurring in women over age 65. Approximately 5% to 10% of ovarian cancers are familial and 3 distinct patterns have been identified: ovarian cancer alone, ovarian and breast cancers, or ovarian and colon cancers.

In most families affected with breast and ovarian cancer syndrome or site-specific ovarian cancer, genetic linkage has been found to BRCA1 and BRCA2. The lifetime risk of developing ovarian cancer in patients harboring germline mutations in BRCA1 is substantially increased.
over the general population. Familial cancer, rather than sporadic cancer, tends to occur at a younger age, but the increased risk in carriers of these mutations is life long, and in some carriers bilateral breast cancer or both breast and ovarian cancer develop. BRCA1 mutation carriers have a greater risk than BRCA2 mutations.

The effectiveness of the surgical procedure used to reduce the risk of breast cancer and/or ovarian cancer and to improve overall survival is also an important parameter in decision-making between prophylactic bilateral mastectomy and prophylactic bilateral salpingo-oophorectomy in a woman with BRCA1 or BRCA2 mutation. There is no randomized or prospective comparative study between these two surgical procedures, and the data available emerge from retrospective or prospective studies between prophylactic surgery and surveillance.

Some experts recommend and many women elect to proceed with prophylactic bilateral salpingo-oophorectomy rather than prophylactic bilateral mastectomy, although the risk of ovarian cancer is substantially lower than the risk of breast cancer. Prophylactic oophorectomy has reduced the risks of both ovarian cancer and breast cancer in earlier small studies. This has been followed by recent large multicenter retrospective analysis of 551 women with a mean follow-up of 9 years. All of these studies provide evidence that oophorectomy can decrease not only the risk of ovarian cancer but also that of breast cancer by approximately 50%.

Finch et al, published the results of a large prospective study of women with the BRCA1 or BRCA2 mutation to estimate the incidence of ovarian, fallopian tube, and primary peritoneal cancer and to estimate the reduction in risk of these cancers associated with a bilateral prophylactic salpingo-oophorectomy. The study included 1,828 BRCA1 and BRCA2 gene mutation carriers participating. Follow-up was for an average of 3.5 years. Five-hundred fifty-five had prophylactic bilateral salpingo-oophorectomy prior to study entry and 490 had the surgery after entry. Results revealed that prophylactic bilateral salpingo-oophorectomy reduced the risk of ovarian and fallopian tube cancer by 80 percent. A residual risk of 4.3 percent for peritoneal cancer remained at 20 years after oophorectomy, but the researchers believe the risk was not sufficiently high to recommend against the surgery.

**November 2009 Update**

Lynch syndrome also called hereditary nonpolyposis colorectal cancer (HNPCC), is the most common of the inherited colon cancer susceptibility syndromes. Those with Lynch syndrome have a markedly increased risk of colorectal cancer and several other cancers including ovarian, upper urologic tract, gastric small bowel, biliary/pancreatic, skin, and brain cancers. Individuals with Lynch Syndrome have a higher than usual risk of developing colorectal cancer (60-80% lifetime risk) and tend to occur before the age of 50. Women with Lynch syndrome have a 40-60% lifetime risk of developing endometrial cancer, a 10 to 12% risk of developing ovarian cancer and an increased risk of developing a second primary colorectal cancer.

A study published in 2006 by Schmeler et al reported on prophylactic surgery to reduce the risk of developing gynecologic cancer for those with Lynch Syndrome. The study included 315 women with documented germ-line mutations associated with Lynch Syndrome. Sixty-one women had undergone prophylactic hysterectomy and 47 women undergone prophylactic bilateral salpingo-oophorectomy were matched with 210 mutation positive women who had not
undergone prophylactic surgery. These matched controls were followed from the date of the surgery until the occurrence of cancer or until the data were censored at the time of the last follow-up visit. There were no occurrences of endometrial, ovarian, or primary peritoneal cancer among those who had undergone prophylactic surgery. Endometrial cancer was diagnosed in 69 women (33%) in the control group for an incidence density of 0.045 per woman-year, Ovarian cancer was diagnosed in 12 women (5%) in the control group for an incidence density of 0.005 per woman-year. Their findings suggest that prophylactic hysterectomy with bilateral salpingo-oophorectomy is an effective strategy for preventing endometrial and ovarian cancer with the Lynch Syndrome.

Key Words:
BRCA1, BRCA2, prophylactic bilateral oophorectomy, prophylactic bilateral salpingo-oophorectomy, ovarian cancer, breast cancer

Approved by Governing Bodies:
Not applicable

Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: No special consideration
Pre-certification requirements: Not applicable

Current Coding:
CPT Codes:

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;

References:


**Policy History:**
Medical Policy Group, December 2005 (1)
Medical Policy Administration Committee, January 2006
Available for comment January 28-March 13, 2006
Medical Policy Group, December 2007 (1)
Medical Policy Group, November 2009 (1)
Medical Policy Administration Committee, November 2009
Available for comment November 6-December 21, 2009
Medical Policy Group, September 2012 (3): Effective September 14, 2012 this policy is no longer scheduled for regular literature reviews and updates.

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.*