Effective November 1, 2023, refer to NCD 230.3 for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Prophylactic Oophorectomy

Policy #: 259
Latest Review Date: February 2023
Category: Surgery
ARCHIVED 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **prophylactic oophorectomy or salpingo-oophorectomy** as a **covered** benefit 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)

For multi-marker serum testing related to ovarian cancer, please refer to MolDX.

Blue Advantage 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 Advantage administers benefits based on the members' contract and 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.

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 maybe 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.

KEY POINTS:

A literature search was performed through February 8, 2023.

Summary of Evidence

For women that receive prophylactic oophorectomy or prophylactic salpingo-oophorectomy for a personal history of breast cancer, BRCA mutation, first degree relatives or first/second degree

relatives (as indicated in policy statement), the evidence consists of meta-analyses, prospective studies, and retrospective studies. 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. The available literature indicates that prophylactic bilateral salpingo-oophorectomy reduced the risk of ovarian and fallopian tube cancer up to 80 percent. A meta-analysis performed in 2016 states that there is "an important component from reducing breast cancer incidence and mortality as well." The evidence is sufficient to determine the technology results in an improvement in health outcome.

For women that receive prophylactive oophorectomy or salpingo-oophorectomy who have a strong family history of colon cancer in first/second degree relatives, or known familial cancer syndrome associated with increased risk of ovarian cancer (e.g. Lynch Syndrome), the evidence consists of prospective studies, retrospective reviews, and cohort studies. 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. Studies show that prophylactic oophorectomy/salpingo-oophorectomy reduces the risk of ovarian cancer in women with Lynch Syndrome. One 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. The evidence is sufficient to determine the technology results in an improvement in health outcome.

Practice Guidelines and Position Statements

The American College of Obstetricians and Gynecologists (ACOG)

ACOG updated their Practice Bulletin regarding Hereditary Breast and Ovarian Cancer Syndrome (Number 182, September 2017). ACOG recommends the following:

- Women with BRCA mutations or who carry another actionable deleterious mutation predisposing to ovarian cancer should be offered risk-reducing bilateral salpingo-oophorectomy. The timing of risk-reducing bilateral salpingo-oophorectomy can be individualized based on the particular genetic mutation, the patient's desires for future childbearing and family history. Typically, risk-reducing salpingo-oophorectomy is recommended at age 35–40 years for BRCA1 carriers with the highest lifetime risk of ovarian cancer, whereas women with BRCA2 may consider delaying until age 40–45 years because of later onset of ovarian cancer. (LOE B)

- In women with BRCA mutations or who have a personal or family history of ovarian cancer, routine ovarian cancer screening with measurement of serum CA 125 level or transvaginal ultrasonography generally is not recommended. Transvaginal ultrasonography or measurement of serum CA 125 level may be reasonable for short-term surveillance in women at high risk of ovarian cancer starting at age 30–35 years until the time they choose to pursue risk-reducing bilateral salpingo-oophorectomy, which is the only proven intervention to reduce ovarian cancer-specific mortality.

ACOG also published a practice bulletin in 2014 related to Lynch Syndrome. They recommend:

- Prophylactic hysterectomy and bilateral salpingo-oophorectomy is a risk reducing option for women with Lynch syndrome who have completed child bearing. In general, risk reducing hysterectomy and salpingo-oophorectomy should be discussed with the patient by their early to mid 40s.

The Society of Gynecologic Oncology

In 2013, the Society of Gynecologic Oncology published a clinical practice statement for salpingectomy for ovarian cancer prevention. They state that "Salpingectomy may be appropriate and feasible as a strategy for ovarian cancer risk reduction."

In 2015, the Society of Gynecologic Oncology recommended the following regarding prophylactic oophorectomy/salpingo-oophorectomy:

- Risk reducing salpingo-oophorectomy (RRSO) between the ages of 35-40 years is recommended for risk reduction in women at increased genetic risk of ovarian cancer. The age of RROS may also be individualized according to the earliest age of onset in they family and personal choices.
- Salpingectomy can be considered at the completion of childbearing in women at increased genetic risk of ovarian cancer who do not agree to salpingo-oophorectomy. However, this is not a substitute for oophorectomy, which should still be performed as soon as the woman is willing to accept menopause, preferably by the age of 40 years. Women delaying or refusing risk-reducing oophorectomy will not receive the breast cancer risk reduction provided by oophorectomy.
- Salpingectomy can be considered in average-risk women undergoing hysterectomy, other pelvic surgery, and sterilization at the completion of childbearing.

U.S. Preventive Services Task Force Recommendations

N/A

KEY WORDS:

BRCA1, BRCA2, prophylactic bilateral oophorectomy, prophylactic bilateral salpingo-oophorectomy, ovarian cancer, breast cancer; Lynch Syndrome, HNPCC

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.

CURRENT CODING:
CPT Codes:

58661	Laparoscopy, surgical; with lysis of adhesions 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;

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POLICY HISTORY:

Adopted for Blue Advantage, January 2006

Available for comment January 26-March 11, 2006
Medical Policy Group, December 2007
Medical Policy Group, November 2009
Available for comment November 6-December 21, 2009
Medical Policy Group, September 2012: Effective September 14, 2012 this policy is no longer scheduled for regular literature reviews and updates.
Medical Policy Group, March 2018
Medical Policy Group, August 2019
Medical Policy Group, February 2021
Medical Policy Group, February 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, February 2023: Reviewed by consensus. No change to policy statements.
Medical Policy Group, November 2023: Archived effective 11/1/2023.
