MEDICAL POLICY

POLICY TITLE	RISK-REDUCING MASTECTOMY AND RISK-REDUCING BILATERAL OOPHORECTOMY OR SALPINGO-OOPHORECTOMY
POLICY NUMBER	MP- 1.036

Original Issue Date (Created):	**10/11/2002**
Most Recent Review Date (Revised):	**2/11/2020**
Effective Date:	**4/1/2020**

I. POLICY

Risk-reducing Mastectomy

Risk-reducing mastectomy may be considered **medically necessary** in patients at high risk of breast cancer. (For definitions of risk levels, see policy guidelines below.)

Contralateral Risk-reducing mastectomy may be considered **medically necessary** in patients who have a personal history of breast cancer.

Risk-reducing mastectomy is considered **investigational** for all other indications. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Risk-reducing Oophorectomy or Salpingo-Oophorectomy

Risk-reducing oophorectomy or salpingo-oophorectomy may be considered **medically necessary** for women with the following conditions:

- Two or more first-degree relatives (e.g., parent, sibling, offspring) with a diagnosis of ovarian cancer; or
- Women with known BRCA1 or BRCA2 mutations confirmed by genetic testing; or
- Women who are beyond child-bearing age (40 years of age or older) who have been diagnosed with a hereditary ovarian cancer syndrome based on a family pedigree constructed by a genetic counselor or physician competent in determining the presence of an autosomal dominant inheritance pattern; or
- Women with a personal history of breast cancer and at least one 1st-degree relative (e.g., parent, sibling, offspring) with a history of ovarian cancer; or
- Women with a known familial cancer syndrome associated with increased risk of ovarian cancer (e.g., hereditary nonpolyposis colorectal cancer [HNPCC] syndrome).

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Policy Guidelines

It is strongly recommended that all candidates for risk-reducing mastectomy undergo counseling regarding cancer risks from a health professional skilled in assessing cancer risk other than the operating surgeon and discussion of the various treatment options, including increased surveillance or chemoprevention with tamoxifen or raloxifene.

There is no standardized method for determining a woman's risk of breast cancer that incorporates all possible risk factors. There are validated risk prediction models, but they are based primarily on family history.

Some known individual risk factors confer a high risk by themselves. The following list includes factors known to indicate a high risk of breast cancer:

- lobular carcinoma in situ,
- a known *BRCA1* or *BRCA2* mutation,
- another gene mutation associated with high risk, e.g., *TP53* (Li-Fraumeni syndrome), *PTEN* (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), *CDH1*, and *STK11*, or
- received radiotherapy to the chest between 10 and 30 years of age.

A number of other factors may increase the risk of breast cancer but do not by themselves indicate high risk (generally considered to be a lifetime risk of greater than or equal to 20%). It is possible that combinations of these factors may be indicative of high risk, but it is not possible to give quantitative estimates of risk. As a result, it may be necessary to individualize the estimate of risk by taking into account numerous risk factors. A number of risk factors, not individually indicating high risk, are included in the National Cancer Institute Breast Cancer Risk Assessment Tool, also called the Gail model.

Another breast cancer risk assessment tool, used in the Women Informed to Screen Depending on Measures of Risk trial, is the Breast Cancer Surveillance Consortium (BCSC) Risk Calculator (https://tools.bcsc-scc.org/bc5yearrisk/calculator.htm). The following information is used in that assessment tool:

- history of breast cancer, ductal carcinoma in situ, breast augmentation, or mastectomy
- age
- race/ethnicity
- number of first-degree relatives (mother, sister, or daughter) diagnosed with breast cancer
- prior breast biopsies (positive or negative)
- BI-RADS breast density (radiologic assessment of breast tissue density by radiologists who interpret mammograms).

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Cross-references

MP-2.211 Genetic Testing for BRCA1 or BRCA2 for Hereditary Breast-Ovarian Cancer Syndrome and other High-Risk Cancers

MP-2.235 Assays of Genetic Expression in Tumor Tissue as a Technique to Determine Prognosis in Patients with Breast Cancer

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

Note **-** The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

III. DESCRIPTION/BACKGROUND

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Risk-reducing mastectomy may be considered in women thought to be at high-risk of developing breast cancer, either due to family history, presence of genetic variants (e.g., *BRCA1*, *BRCA2*), having received radiotherapy to the chest, or the presence of lesions associated with an increased cancer risk such as lobular carcinoma in situ. Lobular carcinoma in situ is both a risk factor for all types of cancer, including bilateral cancer and, in some cases, a precursor to invasive lobular cancer. For those who develop invasive cancer, up to 35% may have bilateral cancer. Therefore, bilateral risk-reducing mastectomy may be performed to eliminate the risk of cancer arising elsewhere; chemoprevention and close surveillance are alternative risk-reduction strategies. Risk-reducing mastectomies are typically bilateral but can also describe a unilateral mastectomy in a patient who has previously undergone or is currently undergoing a mastectomy in the opposite breast for invasive cancer (ie, contralateral risk-reducing mastectomy). Use of contralateral risk-reducing mastectomy has increased in the United States. An analysis of data from the National Cancer Database found that the rate of contralateral risk-reducing mastectomy in women diagnosed with unilateral stage I, II, or III breast cancer increased from approximately 4% in 1998 to 9.4% in 2002.[1]

The appropriateness of a risk-reducing mastectomy is a complicated risk-benefit analysis that requires estimates of a patient's risk of breast cancer, typically based on the patient's family history of breast cancer and other factors. Several models are available to assess risks, such as the Claus model and the Gail model. Breast cancer history in first- and second-degree relatives is

used to estimate breast cancer risk in the Claus model. The Gail model uses the following 5 risk factors: age at evaluation, age at menarche, age at first live birth, the number of breast biopsies, and the number of first-degree relatives with breast cancer. In addition to the patient's risk assessment, the choice of a risk-reducing mastectomy is based on patient tolerance for risk, consideration of changes to appearance and need for additional cosmetic surgery, and the risk-reduction offered by mastectomy vs other options.

Regulatory Status

Mastectomy is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

IV. RATIONALE

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RISK-REDUCING MASTECTOMY

Summary of Evidence
For individuals who have a high risk of breast cancer or extensive mammographic abnormalities precluding excision or biopsy who receive a risk-reducing mastectomy, the evidence includes systematic reviews and observational studies. Relevant outcomes are overall survival, disease-specific survival, functional outcomes, and treatment-related morbidity. Studies have found that a risk-reducing mastectomy lowers subsequent breast cancer incidence and increases survival in select high-risk patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

RISK-REDUCING OOPHERECTOMY

Summary of Evidence
Despite the lack of randomized controlled trials (RCT), the published peer-reviewed medical literature indicates that risk-reducing 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 familial cancer), and only after completion of childbearing. The literature also suggests that a hysterectomy should be performed in conjunction with risk-reducing oophorectomy in women from families with Lynch syndrome. For premenopausal women with early breast cancer, ovarian ablation by oophorectomy is a therapeutic option. It is imperative that women undergoing risk-reducing 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. Specifically, such women should be educated about the increased risk of cardiovascular disease and osteoporosis as a result of surgically-induced

menopause after undergoing oophorectomy with or without hysterectomy (American College of Medical Genetics [ACMG], 1999).

V. DEFINITIONS

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BRCA1 refers to a breast cancer gene that is found in a small percentage of patients with this malignancy and carried by some individuals who will develop breast cancer later in life.

BRCA2 refers to a breast cancer gene found in a small number of patients with breast and ovarian cancers, and carried by some individuals who will develop breast cancer later in life.

FIRST-DEGREE RELATIVE refers to a parent, sibling, or child.

GENE is the basic unit of heredity, the code for a specific protein.

HYPERPLASIA refers to excessive proliferation of normal cells in the normal tissue arrangement of an organ.

IN SITU means in position, localized.

MUTATION is an unusual change in genetic material occurring spontaneously or by induction.

OVARIAN CANCER is an abnormal, malignant growth located in the ovaries.

P53 GENE is a tumor suppressor gene that normally inhibits the growth of tumors. This gene is altered in many types of cancer.

PTEN GENE is a tumor suppressor gene that normally inhibits the growth of tumors. This gene is altered in many types of cancer.

RISK-REDUCING OOPHORECTOMY refers to the elective surgical removal of ovaries, before cancer develops, in women at high risk for ovarian cancer due to a family history of the disease.

SECOND-DEGREE RELATIVE refers to aunt, uncle, niece, nephew, or grandparent.

THIRD-DEGREE RELATIVE refers to a great aunt/uncle, first cousin or great grandmother/grandfather**.**

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VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
19303	58661	58720	58940					

ICD-10-CM Diagnosis Codes	Description
D05.00	Lobular carcinoma in situ of unspecified breast
D05.01	Lobular carcinoma in situ of right breast
D05.02	Lobular carcinoma in situ of left breast
R92.1	Mammographic calcification found on diagnostic imaging of breast
Z15.01	Genetic susceptibility to malignant neoplasm breast
Z15.02	Genetic susceptibility to malignant neoplasm of ovary
Z40.01	Encounter for prophylactic removal of breast
Z40.02	Encounter for prophylactic removal of ovary

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ICD-10-CM Diagnosis Codes	Description
Z80.3	Family history of malignant neoplasm of breast
Z80.41	Family history of malignant neoplasm of ovary
Z84.81	Family history of carrier of genetic disease
Z85.3	Personal history of malignant neoplasm of breast
Z92.3	Personal history of irradiation

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.036	**CAC 10/29/02**
	CAC 1/28/03
	CAC 1/27/04
	CAC 2/22/05
	CAC 3/28/06
	CAC 3/27/07
	CAC 5/27/08
	12/12/08 Definition Change
	CAC 9/29/09 Policy criteria for prophylactic mastectomy revised with additional indications (PTEN and p53 mutations)
	CAC 11/30/10 Consensus Review
	CAC 11/22/11 Consensus Review

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	04/05/2013 Deleted codes removed from policy
	7/24/13 Admin coding review complete
	CAC 9/24/13. Minor review. For prophylactic mastectomy. Definition of high risk clarified and medically necessary indication for those at moderately increased risk of breast cancer removed, except for women with extensive mammographic abnormalities. New investigational statement added for contralateral prophylactic mastectomy among women with cancer in the other breast who do not meet one of the medically indicated conditions. No change to prophylactic oophorectomy policy statements.
	CAC 9/30/14 Consensus review. References updated; rationale added. No changes to the policy statements.
	CAC 6/2/15 Minor review**.** Added other gene mutations associated with increased risk to policy guidelines. (e.g., PTEN, TP53, CDH1, and STK11). Updated rationale and references. Coding reviewed.
	CAC 5/31/16 Minor revision. Medically necessary statement on lobular carcinoma in situ removed and added to high-risk criteria in the policy guidelines. Also in the policy guidelines, "20% to 25%" changed to "20%", revised bullet points on high risk mutations in relatives with genetic syndromes and added wording on characteristics that may increase risk in combination with other factors. Guidelines, rationale, and references updated. Coding reviewed.
	Administrative Update 11/22/16 Variation reformatting
	CAC 3/28/17 Minor revision. Contralateral prophylactic mastectomy may now be considered medically necessary in patients who have a personal history of breast cancer. Coding reviewed.
	Admin update 10/1/17: Added new ICD 10 code effective from 10/1/17 and revised old ICD 10 codes.
	1/12/18 Minor revision. Prophylactic mastectomy section: Medically necessary statement on extensive mammographic abnormalities removed. Prophylactic Oophorectomy policy statement updated to include salpingo-oophorectomy and coverage expanded. Title changed. Description/Background, Rationale and Reference sections updated. Coding Reviewed.
	1/17/19 Consensus review. "Prophylactic" mastectomy changed to "Risk-Reducing" mastectomy throughout policy to reflect preferred terminology in the literature and by NCCN; intent of the statements remains unchanged. Title changed to "Risk-Reducing Mastectomy and Risk Reducing Bilateral Oophorectomy or Salpingo-Oophorectomy.
	01/01/20 Coding update. Deleted code removed from policy, 19304.
	2/11/20 Consensus review. No change to policy statement. References updated, coding reviewed.