



### Risk Reduction Mastectomy SRG-016

<b>Iowa Medicaid Program:</b>	Claims Pre-Pay	<b>Effective Date:</b>	1/21/2011
<b>Revision Number:</b>	12	<b>Last Rev Date:</b>	7/19/2024
<b>Reviewed By:</b>	Medicaid Medical Director	<b>Next Rev Date:</b>	7/18/2025
<b>Approved By:</b>	Medicaid Clinical Advisory Committee	<b>Approved Date:</b>	7/24/2020

#### Descriptive Narrative

Risk-reduction mastectomy (RRM) refers to surgical removal of the breasts in the absence of malignancy to reduce breast cancer risk in women. RRM is synonymous with *prophylactic mastectomy* and is further specified as either bilateral or contralateral. Bilateral RRM refers to removal of both breasts in asymptomatic women, while contralateral RRM refers to removal of the unaffected breast when bilateral mastectomy is performed for the management of unilateral breast cancer.

In high-risk patients, RRM is associated with reduction in breast cancer risk and potential adverse effects on quality of life. Thus, prior to any RRM procedure, patients should be informed of the potential for both benefit and harm. Potential risks may include wound complications, unanticipated additional surgical procedures, and adverse effects on quality of life.

The discovery in recent years of the gene mutations BRCA 1 and BRCA 2, as well as the development of predictive models to determine an individual's lifetime risk of developing breast cancer, have provided additional tools to help a woman determine the potential benefits of this procedure.

## Criteria

Risk-reduction mastectomy is considered medically necessary when **ALL** the following have been met:

1. Significantly elevated risk of breast cancer as indicated by **ONE** or more of the following:
  - a. Patient has BRCA1 or BRCA2 genetic mutation, Li-Fraumeni syndrome (TP53 mutation), or Cowden syndrome (PTEN mutation), **OR**
  - b. Lifetime risk of new breast cancer diagnosis estimated to be greater than 20 percent (e.g., based upon models largely dependent on family history such as Claus, Tyrer-Cuzick, BRCAPRO, or BOADICEA); **OR**
  - c. History of chest wall irradiation for Hodgkin lymphoma or other malignancies before 30 years of age; **OR**
  - d. History of breast cancer in the contralateral breast; **OR**
  - e. Extensive mammographic abnormalities (e.g., calcifications) exist such that adequate biopsy is impossible, **OR**
  - f. Noninvasive histology indicating risk (e.g., lobular carcinoma in situ or atypical hyperplasia); **AND**
2. Alternative approaches to elevated risk such as screening (with mammography and breast magnetic resonance imaging) and chemoprevention (e.g., medications administered for 5 years) not deemed sufficient by member; **AND**
3. At least 10-year life expectancy.

## Coding

The following list of codes is provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

HCPCS	Description
19303	Mastectomy, simple, complete.

## Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

## References

Glannakeas V. Lim DW. Narod SA. Bilateral Mastectomy and Breast Cancer Mortality. JAMA Oncology. Published online July 25, 2024

Khan SA. Kocherginsky M. Contralateral Breast Cancer Remains a Complex Biological Conundrum. Editorial. JAMA Oncology. Published online July 25, 2024.

Chagpar AB. Contralateral prophylactic mastectomy. UpToDate. Topic last updated: August 24, 2023.

Preventive Surgery to Reduce Breast Cancer Risk. American Cancer Society. Last Revised: December 16, 2021.

Surgery to Reduce the Risk of Breast Cancer. National Cancer Institute. Reviewed: June 26, 2024

Breast Cancer Risk Reduction. NCCN Clinical Practice Guidelines in Oncology. National Comprehensive Cancer Network. Version 22024 – March 11, 2024

Jatoi I. Kemp Z. Risk-Reducing Mastectomy. JAMA Insights. Women's Health. JAMA May 4, 2021. Volume 325, Number 17. Pp. 1781-1782.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

## Criteria Change History

Change Date	Changed By	Description of Change	Version
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Change Date	Changed By	Description of Change	Version
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Change Date	Changed By	Description of Change	Version
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7/19/2024	CAC	Annual review.	12
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William (Bill) Jagiello, DO



Change Date	Changed By	Description of Change	Version
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7/21/2024	CAC	Annual review.	11
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## Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
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7/15/2022	CAC	Annual review.	10
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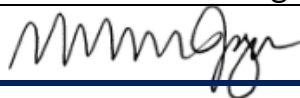


Change Date	Changed By	Description of Change	Version
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7/16/2021	CAC	Revised Descriptive Narrative. Tweaked Criteria. Enhanced Coding. Added Compliance section. Added reference. Formatting changes.	9
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Change Date	Changed By	Description of Change	Version
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7/17/2020	Medical Director	Added narrative, changed criteria, removed code 19304.	8
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**Criteria Change History (continued)**

<b>Change Date</b>	<b>Changed By</b>	<b>Description of Change</b>	<b>Version</b>
7/15/2016	Medical Director	Criterion #1 added additional four syndromes. Added Genetic Home Reference NIH.	7

**Signature**

C. David Smith, MD



<b>Change Date</b>	<b>Changed By</b>	<b>Description of Change</b>	<b>Version</b>
7/17/2015	CAC	Added last paragraph in References.	6

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<b>Change Date</b>	<b>Changed By</b>	<b>Description of Change</b>	<b>Version</b>
7/14/2015	Medical Director	Criterion #1 added “including rearrangements detected via BRAT”.	5

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<b>Change Date</b>	<b>Changed By</b>	<b>Description of Change</b>	<b>Version</b>
7/18/2014	Medical Director	Formatting changes.	4

<b>Change Date</b>	<b>Changed By</b>	<b>Description of Change</b>	<b>Version</b>
7/19/2013	CAC	Changed criteria to a member must meet criterion #1 or criterion #2 AND one of criterion #3.	3

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<b>Change Date</b>	<b>Changed By</b>	<b>Description of Change</b>	<b>Version</b>
3/26/2013	Medical Director	Added HCPCs Codes. Added References.	2

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<b>Change Date</b>	<b>Changed By</b>	<b>Description of Change</b>	<b>Version</b>
1/18/2013	CAC	Criteria - changed “all” of the following to “2” of the following.	1

**Signature**