

Medical Coverage Policy

Effective Date: 03/27/2014 Revision Date: 03/27/2014 Review Date: 03/27/2014 Policy Number: CLPD-0456-007

Change Summary: Updated Description, Coverage Determination, References

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Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.gov. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from Humana.

Description

Prophylactic mastectomy is the surgical removal of one or both breasts, at a time when there is no known breast cancer, in order to decrease future risk of developing breast cancer. Prophylactic mastectomy may reduce the risk of breast cancer by as much as 97%. There are different types of mastectomies, each of which can be performed on one (single) or both (double) breasts.

Total or simple mastectomy removes all of the breast tissue, including the nipple, the areola and the overlying skin, but does not dissect lymph nodes or remove chest muscle tissue beneath the breast. This procedure is considered the preferred option for preventive surgery in women at very high risk for breast cancer.

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A **skin-sparing mastectomy (SSM)** involves the removal of breast tissue, the nipple and the areola, but leaves the majority of the breast skin intact for use during breast reconstruction. SSM is a type of subcutaneous mastectomy.

A **nipple sparing mastectomy** (NSM), also a type of subcutaneous mastectomy, is performed much the same as the SSM but preserves the skin of the nipple and areola Enough breast tissue may be left behind to require yearly screening mammograms.

With any type of mastectomy, it is not possible to remove all breast tissue that may be at risk of becoming cancerous in the future. Because breast tissue may sometimes be found in the chest wall, axilla, above the collarbone or in the abdomen, it is impossible for a surgeon to remove all of this tissue.¹

It is not possible to determine whether prophylactic mastectomy will benefit a particular woman. Some women who have genes associated with familial breast cancer, known as BRCA1 and BRCA2 mutations, are at risk for developing breast cancer early in life and a prophylactic mastectomy before the cancer occurs might add many years to their lives. While most women with BRCA mutations develop breast cancer, some do not.²

Coverage Determination

Any state mandates for prophylactic mastectomy take precedence over this clinical policy.

Humana members may be eligible under the Plan for a **prophylactic mastectomy** for the following **personal risk** indications:

- History of radiation therapy to the chest prior to age 30; OR
- Known deleterious or suspected deleterious mutation in a breast cancer susceptibility gene (e.g., BRCA 1/2, PTEN, TP53) proven by genetic testing (Refer to <u>Genetic Testing and Genetic Counseling for Hereditary Cancer Syndromes</u> Medical Coverage Policy); OR
- Personal history of breast cancer; OR
- Presence of atypical hyperplasia of lobular or ductal origin and/or lobular

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carcinoma in situ confirmed on biopsy with dense, fibronodular breasts that are mammographically or clinically difficult to evaluate.³

Humana members may be eligible under the Plan for a **prophylactic mastectomy** for the following **family risk** indications:

- First-, second- or third-degree blood relative with a known deleterious or suspected deleterious mutation in a breast cancer susceptibility gene (e.g., BRCA 1/2, PTEN, TP53) proven by genetic testing (Refer to <u>Genetic Testing and Genetic</u> Counseling for Hereditary Cancer Syndromes Medical Coverage Policy); OR
- Two or more primary breast cancers (in a single individual) in a first- or seconddegree blood relative; OR
- Two or more first- and/or second-degree blood relatives, on the same side of the family, diagnosed with primary breast cancer; **OR**
- First- or second-degree blood relative diagnosed with primary ovarian cancer; **OR**
- First- or second-degree blood relative with breast cancer diagnosed at less than 45 years of age; OR
- First- or second-degree blood relative with a combination of breast cancer; AND one or more of the following:
 - Adrenocortical carcinoma
 - Aggressive prostate cancer (Gleason score greater than or equal to 7)
 - Brain tumors
 - Dermatologic manifestations (mucocutaneous lesions, such as one biopsy proven trichilemmoma, multiple palmoplantar keratoses, multifocal or extensive oral mucosal papillomatosis, multiple cutaneous facial papules, often verrucous) and/or macrocephaly (i.e., greater than or equal to 58 cm in adult women, 60 cm in adult men)

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- Diffuse gastric cancer
- Endometrial cancer
- Hamartomatous polyps of GI tract
- Leukemia/lymphoma
- Pancreatic cancer
- Sarcoma
- Thyroid cancer; OR
- Ethnicity associated with higher mutation frequency (e.g., women of Ashkenazi Jewish descent with breast, ovarian or pancreatic cancer at any age); **OR**
- First- or second degree blood relative diagnosed with male breast cancer at any age; OR
- First- or second degree blood relative diagnosed with ovarian/fallopian tube cancer or primary peritoneal cancer at any age⁴

First, Second and Third Degree Relatives - An individual's close blood family members are defined as follows:

- First degree relatives Parents, full siblings or children
- **Second degree relatives** Aunts, uncles, grandparents, grandchildren, nieces, nephews or half-siblings
- Third degree relatives Great grandparents, great aunts, great uncles or first cousins

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Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **prophylactic mastectomy** for any indications other than those listed above. All other indications are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Background

Additional information about **familial breast cancer** may be found from the following websites:

- American Cancer Society http://www.cancer.org
- National Cancer Institute http://www.cancer.gov
- National Comprehensive Cancer Network http://www.nccn.org
- National Library of Medicine http://www.nlm.nih.gov

Medical Alternatives

Alternatives to **prophylactic mastectomy** include, but may not be limited to, the following:

- Breast Magnetic Resonance Imaging (MRI) as an adjunct to clinical breast exam and mammogram. (Refer to <u>Breast Imaging</u> Medical Coverage Policy)
- Frequent monitoring by a physician that includes clinical breast exams and mammograms
- Prescription drug therapy may be appropriate for this condition

To make the best health decision for the patient's individual needs, the patient should consult his/her physician.

Humana may offer a disease management program for this condition. **The patient may call the number on his/her member identification card to ask about our programs to help manage his/her care**.

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Provider Claims Codes

Any CPT, HCPCS or ICD codes listed on this medical coverage policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
19303	Mastectomy, simple, complete	
19304	Mastectomy, subcutaneous	
CPT®		
Category III Code(s)	Description	Comments
No code(s) identified		
HCPCS Code(s)	Description	Comments
No code(s) identified		
ICD-9 Procedure Code(s)	Description	Comments
85.34	Other unilateral subcutaneous mammectomy	
85.36	Other bilateral subcutaneous mammectomy	
85.41	Unilateral simple mastectomy	
85.42	Bilateral simple mastectomy	

Medical Terms

Adrenal Gland - Either of a pair of complex endocrine organs located above each kidney that produce a variety of hormones.

Adrenocortical - Of, relating to or derived from the cortex (outer surface) of the adrenal glands.

Aesthetic - Concerned with beauty, artistic impact or appearance.

Areola - Dark area of skin that surrounds the nipple of the breast.

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Atypical Hyperplasia - Benign (noncancerous) condition in which cells have abnormal features and are increased in number.

Axilla - Underarm; armpit.

BRCA1 - Gene located on the seventeenth chromosome and associated with a risk of breast and ovarian cancer.

BRCA2 - Gene located on the thirteenth chromosome and associated with a risk of breast cancer.

Carcinoma - A malignant tumor of epithelial origin.

Deleterious - Harmful, injurious.

Epithelial - Membranous tissue composed of one or more layers of cells separated by very little intercellular substance and forming the covering of most internal and external surfaces of the body and its organs.

Familial - Tending to occur in more members of a family than expected by chance alone.

Fibronodular - A rounded or irregular shaped cluster of cells made up of fibrous tissue.

Gleason Score - A system of grading prostate cancer tissue from two to ten by microscopic appearance. A low Gleason score indicates the cancer tissue is similar to normal prostate tissue and is less likely to spread; a high Gleason score means the cancer tissue is very different from normal and is more likely to spread.

Hamartomatous - A mass resembling a tumor that represents unusual, irregular or unexpected development of tissue natural to a part or organ rather than a true tumor.

Keratoses - A disease of the skin marked by overgrowth of horny tissue which is composed of tough fibrous material consisting chiefly of keratin (e.g., hair and nails).

Lobular Carcinoma in Situ - Changes that are found in the cells in the lining of the lobules or lobes of the breast.

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Magnetic Resonance Imaging (MRI) - Noninvasive body imaging procedure that uses powerful magnets and radio waves to construct pictures of the internal structures of the body.

Mammogram - X-ray of the breast used to detect and diagnose breast disease.

Mastectomy - Surgical removal of all or part of the breast and sometimes associated lymph nodes and muscle.

Mutation - Sudden change from the parent type in one or more heritable characteristics, caused by a change in a gene or a chromosome.

Nipple - Tip of the breast; the pigmented projection in the middle of the areola contains the opening of milk ducts from the breast.

Oncology - Study of cancer.

Papillomatosis - Condition marked by the presence of numerous papillomas, benign tumors resulting from an overgrowth of epithelial tissue.

Papule - A small solid usually conical elevation of the skin caused by inflammation, accumulated secretion or hypertrophy (over growth) of tissue.

Prophylactic - Guarding from or preventing the spread or occurrence of disease or infection.

Sarcoma - A malignant tumor arising from connective tissue, bone, cartilage or striated muscle that spreads by extension into neighboring tissue or by way of the bloodstream.

Skin Flap - Full-thickness mass or flap of tissue containing epidermis, dermis and subcutaneous tissue.

Specimen - A portion of material for use in testing, examination or study.

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Subcutaneous - Pertaining to the fatty layer under the skin.

Trichilemmoma - A benign skin tumor arising from cells of a hair follicle.

Verrucous - Characterized by the formation of warty lesions.

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