

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: MP.101.MH
Last Review Date: 11/12/2015
Effective Date: 01/01/2016
Renewal Date: 01/01/2017

MP.101.MH – Prophylactic Mastectomy

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar MA – DSNP – CSNP
- ✓ MedStar CareFirst PPO

MedStar Health considers Prophylactic Mastectomy medically necessary for the following indications:

Prophylactic Mastectomy is considered medically necessary for members at high risk of breast cancer when the member has **at least one** of the following criteria:

1. Personal history of breast cancer and one or more of the following:
 - a. Diagnosed age \leq 45 years
 - b. Two breast cancer primaries, when first breast cancer was diagnosed age \leq 50 years,
 - c. Diagnosed age \leq 50 years with one or more close blood relative with breast cancer at any age or with a limited family history,
 - d. Diagnosed age \leq 60 years with a triple negative breast cancer,
 - e. Diagnosed at any age with one or more close blood relative breast cancer diagnosed \leq 50 years,
 - f. Diagnosed at any age with two or more close blood relatives with breast cancer diagnosed any age,
 - g. Diagnosed at any age with one or more close blood relative with epithelial ovarian cancer,
 - h. Diagnosed at any age with two or more close blood relatives with pancreatic cancer or aggressive prostate cancer (Gleason score \geq 7) at any age,
 - i. Close male blood relative with breast cancer,
 - j. Personal history of male breast cancer,
 - k. For an individual of an ethnicity associated with a higher mutation frequency (eg Ashkenazi Jewish) no additional family history may be required.
2. Personal history of epithelial ovarian, fallopian tube, or primary peritoneal cancer,
3. Personal history of pancreatic cancer or aggressive prostate cancer (Gleason score \geq 7) at any age with \geq 2 close blood relatives with breast and/or ovarian and/or pancreatic or aggressive prostate cancer (Gleason score \geq 7) at any age.
4. Two or more first-degree relatives with breast cancer.

MP.101.MH – Prophylactic Mastectomy

Policy Number: MP.101.MH
Last Review Date: 11/12/2015
Effective Date: 01/01/2016
Renewal Date: 01/01/2017

5. One first-degree relative and two or more second-or third-degree relatives with breast cancer.
6. One first-degree relative with breast cancer before the age of 45 years and another relative with breast cancer.
7. One first-degree relative with breast cancer and one or more relatives with ovarian cancer.
8. Two second- or third-degree relatives with breast cancer and one or more with ovarian cancer.
9. One second- or third-degree relative with breast cancer and two or more with ovarian cancer.
10. Three or more second- or third-degree relatives with breast cancer.
11. One first-degree relative with bilateral breast cancer.
12. The presence of a BRCA1 or BRCA2 mutation. (Refer to PA-055 Molecular Susceptibility Testing for Breast Cancer and Ovarian Cancer policy).
13. The presence of a TP53 or PTEN mutation.
14. History of prior thoracic radiation therapy (such as for Hodgkin's disease) <30 years of age.
15. Extensive mammographic abnormalities (e.g., calcifications) exist such that adequate biopsy is impossible and strong concern about breast cancer risk.
16. Additional criteria for CPM includes **at least one** of the following:
 - a. Diagnosis of invasive ductal or lobular carcinoma.
 - b. Ductal Carcinoma in situ (DCIS) of intermediate or high grade or LCIS with features of pleomorphic lobular carcinoma.

Blood or tissue samples from other non covered family members occasionally are required to provide the medical information necessary for the proper medical care of a member. Such testing for molecular-based testing for BRCA and other specific heritable disorders in non-members is considered medically necessary when **all** of the following conditions are met:

- The information is needed to adequately assess risk in the member
- The information will be used in the immediate care plan of the member and
- The non covered family member's benefit plan (if any) will not cover the test and the denial is based on specific plan exclusion

Limitations

1. Genetic testing of a non-covered family member of a covered member for the sole purpose of obtaining non-related genetic information is not covered
2. Prophylactic mastectomy:
 - Subcutaneous Prophylactic Mastectomy is not recommended for coverage.
 - A board certified or board eligible surgeon with expertise in breast cancer must recommend the Prophylactic Mastectomy.

MP.101.MH – Prophylactic Mastectomy

Policy Number: MP.101.MH
Last Review Date: 11/12/2015
Effective Date: 01/01/2016
Renewal Date: 01/01/2017

- When the indication for Prophylactic Mastectomy is based on pathology, a board certified or board eligible Pathologist must validate the report.

See Also:

PA.055.MH Molecular Susceptibility Testing for Breast and Ovarian Cancer

Background

BreastCancer.org defines prophylactic mastectomy as a surgery that removes one or both breasts to reduce the risk of developing breast cancer. According to the National Cancer Institute, prophylactic mastectomy in high-risk women may be able to reduce the risk of developing breast cancer by 90%.

High-risk individuals may include:

- Family history of breast cancer, especially before age 50
- Tested positive for BRCA1, BRCA2, or PALB2 gene mutations
- Diagnosis of lobular carcinoma in situ (LCIS)
- Radiation therapy to the chest prior to age 30
- Widely spread breast microcalcifications and/or dense breasts

When prophylactic mastectomy is being considered, the National Comprehensive Cancer Network (NCCN) Guidelines note that the small benefits must be balanced with the risk of recurrent disease from the known breast cancer, the psychological and social issues associated with bilateral mastectomy, and the overall risks of contralateral mastectomy.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
CPT Codes	
19303	Mastectomy, simple, complete

References

1. Agency for Healthcare Research and Quality (AHRQ): National Guideline Clearinghouse. Guideline Summary NGC-9400. Risk reduction and surveillance strategies for individuals at high genetic risk for breast and ovarian cancer. Released April 2011. Summary completed by ECRI Institute: December 20, 2012.
<http://www.guideline.gov/content.aspx?id=38601&search=prophylactic+mastectomy>

MP.101.MH – Prophylactic Mastectomy

Policy Number: MP.101.MH
Last Review Date: 11/12/2015
Effective Date: 01/01/2016
Renewal Date: 01/01/2017

2. Breastcancer.org. Prophylactic Mastectomy. Last modified October 14, 2015. http://www.breastcancer.org/treatment/surgery/prophylactic_mast
3. Hayes Medical Technology Directory. Prophylactic Oophorectomy for the Prevention of Ovarian Cancer. Annual Review December 9, 2014.
4. Hayes Medical Technology Directory. Risk Reducing (Prophylactic) Mastectomy. Annual review December 11, 2014.
5. Med News Today: Updated NCCN Guidelines For Breast Cancer Discourages Prophylactic Mastectomy In Women Other Than Those At High Risk. Dated: 10/29/2009. <http://www.medicalnewstoday.com/articles/169085.php>
6. National Cancer Comprehensive Cancer Network, NCCN Clinical Practice Guidelines in Oncology™. Version 1.2014. Genetic /Familial High Risk Assessment: Breast and Ovarian Cancer. Issued February 28, 2014. http://www.nccn.org/professionals/physician_gls/pdf/genetics_screening.pdf
7. National Cancer Institute- National Institutes of Health. FactSheet-Surgery to Reduce the Risk of Breast Cancer. Reviewed August 12, 2013. <http://www.cancer.gov/cancertopics/factsheet/Therapy/risk-reducing-surgery>
8. National Comprehensive Cancer Network: NCCN Clinical Practice Guidelines in Oncology™. Version 1.2014- Breast Cancer Risk Reduction, Issued June 9, 2014. http://www.nccn.org/professionals/physician_gls/pdf/breast_risk.pdf
9. Schmeler KM, Sun CC, Bodurka DC, et al. Prophylactic bilateral salpingo-oophorectomy compared with surveillance in women with BRCA mutations. *Obstet Gynecol.* 2006 Sep;108(3 Pt 1):515-520. <http://www.ncbi.nlm.nih.gov/pubmed/16946209>
10. Society of Gynecologic Oncologists. SGO Committee Statement: Clinical Practice Committee Statement on Prophylactic Salpingo-oophorectomy. *Gynecol Oncol.* 2005 Aug; 98(2): 179-181. http://ac.els-cdn.com/S0090825805003227/1-s2.0-S0090825805003227-main.pdf?_tid=593f094e-1db7-11e4-acbe-00000aacb35d&acdnat=1407363584_23cfdffce6da11a61f35eb23932d4870
11. Tuttle TM. American College of Surgeons- Contralateral Prophylactic Mastectomy May Not Significantly Increase Life Expectancy in Women with Early-Stage Breast Cancer: New Decision-Making Model Helps Women with Early-Stage Breast Cancer Decided on Most Appropriate Treatment. Released October 7, 2013. <http://www.facs.org/clincon2013/press/tuttle.html>

Disclaimer:

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable

MP.101.MH – Prophylactic Mastectomy

Policy Number: MP.101.MH

Last Review Date: 11/12/2015

Effective Date: 01/01/2016

Renewal Date: 01/01/2017

Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of Evolent Health. Any sale, copying, or dissemination of said policies is prohibited.