Insurance Coverage of Prophylactic Mastectomies: A National Review of the United States

Michael Ha, MA Cantab MB BChir,[1] Ledibabari M. Ngaage, MA Cantab MB BChir,[1,2] Emily R. Finkelstein, MD,[1,3] Marissa Klein, BS,[1] Annie Yanga, BS,[1] Shannon M. Colohan, Mac,[4] Suliat M. Nurudeen, MD, MPH,[5] Julia H. Terhune, MD,[5] Sheri Slezak, MD,[1] Yvonne M. Rasko, MD[1]

Abstract

Prophylactic mastectomy (PM) may be a suitable risk-reducing procedure. However, there are substantial discrepancies between national society recommendations and insurance company requirements. One-hundred insurance company policies on PM were evaluated, yielding significant variability in both indications and medical necessity criteria between insurers. The decision to undergo a PM must be carefully considered and should not be influenced by insurance coverage.

Background: Breast cancer is associated with a multitude of risk factors, such as genetic predisposition and mutations, family history, personal medical history, or previous radiotherapy. A prophylactic mastectomy (PM) may be considered a suitable risk-reducing procedure in some cases. However, there are significant discrepancies between national society recommendations and insurance company requirements for PM. **Materials and Methods:** The authors conducted a cross-sectional analysis of insurance policies for a PM. One-hundred companies were selected based on the greatest state enrolment and market share. Their policies were identified through a Web-based search and telephone interviews, and their medical necessity criteria were extracted. **Results:** Preauthorized coverage of PMs was provided by 39% of insurance policies (n = 39) and 5 indications were identified. There was consensus amongst these policies to cover a PM for BRCA1/2 mutations (n = 39, 100%), but was more variable for other genetic mutations (15%-90%). Coverage of PM for the remaining indications varied among insurers: previous radiotherapy (92%), pathological changes in the breast (3%-92%), personal history of cancer (64%) and family history risk factors (39%-51%). **Conclusion:** There is a marked level of variability in both the indications and medical necessity criteria for PM insurance policies. The decision to undergo a PM must be carefully considered with a patient's care team and should not be affected by insurance coverage status.

Clinical Breast Cancer, Vol. 23, No. 2, 211–218

Keywords: Breast, Breast neoplasms, Hereditary cancer syndromes, Insurance XCoverage, Mastectomy, Prophylactic mastectomy, Prophylactic surgical procedures, Risk reduction

Introduction

In the United States, 13% of women will be diagnosed with breast cancer in their lifetime, with 276,480 estimated new cases in 2020.[1] A multitude of risk factors are associated with the development of breast cancer, including: genetic predisposition and susceptibility, family history, personal medical history, exogenous hormone intake, lifestyle patterns, and anthropomorphic characteristics.[2-5] Due to its mortality and predictive risk factors, there has been a growing global initiative for the early detection and prevention of breast cancer,[2,6] and some high-risk patients may consider a prophylactic mastectomy (PM).

PM were initially recommended as a preventative measure in breast cancer for those possessing a BRCA1/BRCA2 mutation.[7] Since then, they have become more popular for a variety of high-risk indications, both with and without a concurrent diagnosis of breast cancer.[8–10] However, the definition of "high-risk" can be difficult, multifaceted, and require a considered discussion between a patient and their health care team. This is evident in a statement by the Society of Surgical Oncology (SSO), who attempted

[1]Division of Plastic Surgery, Department of Surgery, University of Maryland School of Medicine, Baltimore, MD
[2]Department of Plastic and Reconstructive Surgery, Johns Hopkins University, Baltimore, MD
[3]Division of Plastic and Reconstructive Surgery, University of Miami Miller School of Medicine, Miami, FL
[4]Division of Plastic Surgery, Department of Surgery, University of Washington, Seattle, WA
[5]Department of Surgery, University of Maryland School of Medicine, Baltimore, MD

Submitted: Sep 21, 2022; Accepted: Dec 1, 2022; Epub: 5 December 2022

Address for correspondence: Emily Finkelstein, Division of Plastic Surgery, University of Maryland Medical Center, 22 S Greene St. MD, 21230.
E-mail contact: erf92@miami.edu

1526-8209/$ - see front matter
https://doi.org/10.1016/j.clbc.2022.12.001

Table 1 Recommended Indications for Prophylactic Mastectomies by SSO,[11] ASBrS,[12] and ASPS[13]

SSO	ASBrS[a]	ASPS
Gene mutation	Proven or suspected genetic susceptibility	Genetic susceptibility to malignant neoplasm of breast
Familial history (as predicted by risk assessment model)		Family history of malignant neoplasm of breast
Pathogenic changes in breast tissue		Carcinoma in situ of the breast
Prior chest wall irradiation	History of prior radiotherapy	Personal history of irradiation
Breast density		Neoplasm of uncertain behaviour of breast
Other factors[b]		Fibrocystic breast disease
		Personal history of malignant neoplasm of breast

Abbreviations: ASBrS = American Society of Breast Surgeons; ASPS = American Society of Plastic Surgery; SSO = Society of Surgical Oncology.
[a] Contralateral prophylactic mastectomy is discouraged in average-risk women with unilateral breast cancer
[b] Multiple modifiable and nonmodifiable factors that contribute a small increase in relative risk individually (1.5-2.0), such as bone mineral density, alcohol consumption, circulating insulin and oestrogen levels.

to outline the indications in which a PM may be considered.[11] This was mirrored in a similar set of guidelines by the American Society of Breast Surgeons (ASBrS)[12] and American Society of Plastic Surgery (ASPS)[13] with common themes between the 2 societies (Table 1). Furthermore, a patient's comorbidities, socioeconomic background, and insurance coverage also play a role in the decision for a PM.[14] In fact, a patient's access to private medical insurance can be a significant predictive factor for the receival of a PM.[15] Despite this, there is often a significant variability between insurance coverage that can lead to inequalities in the access to procedures, and limits even their discussion of medical necessity.[16,17] Previously, the authors have discussed the variability in coverage of contralateral prophylactic mastectomies in the setting of a breast cancer diagnosis.[18] However, the literature is void on the insurance coverage for bilateral or contralateral prophylactic mastectomies noncancerous "high-risk" indications.

This study aims to assess the insurance coverage for PM in patients without diagnosed breast cancer, and the variability in indications and medical necessity criteria. We will also compare whether insurance policies' definition of high-risk patients reflects national recommendations of SSO, ASBrS, and ASPS.

Material and Methods

We selected the 100 largest and most popular third-party payers in America, including Medicare and Medicaid. This was based on state enrolment and company market share, as reported by the Henry Kaiser Foundation and National Association of Insurance Commissioners.[19,20] A web-based search was conducted to identify the policies related to prophylactic mastectomies from the corresponding company's website. If a policy was not available online, we communicated with the company directly via telephone call or email, and if a lack of established criteria for surgical intervention was confirmed, the insurance company was deemed not to have a policy for PM surgery. Policies were categorized into 3 groups based on coverage status: never covered, covered on a case-by-case basis, and covered with pre-authorization. Case-by-case status was defined as a policy established for coverage but without standardized criteria for determining medical necessity and coverage determined only with specific patient details.

The insurance policies with medical necessity criteria were analyzed and compared to the recommendations from SSO[11], ASBrS[12], and ASPS.[13] The coverage eligibility criteria were extracted and divided into 5 indications based on SSO, ASBrS, and ASPS recommendations: genetic susceptibility, familial history, irradiation history, personal history of malignant neoplasm, and pathological changes in the breast (Table 1). Family history was categorized into 2 groups based on the guideline that defined them. The first is by ASPS and includes specific scenarios in which a PM would be covered, such as "a first degree relative with bilateral breast cancer" or "3 or more second/third degree relatives with breast cancer.". In contrast, the second group encompasses nonspecific criteria in which a patient had to demonstrate a significant breast cancer risk from multiple factors including their family history. This is more reflective of SSO's discussion of family history. Family history is not included in ASBrS recommendations.

Data were compiled and analyzed in Microsoft Excel (Microsoft Corp., Redmond, WA). Categorical variables were compared using chi-squared test and Fisher's exact test, as appropriate. Statistical significance was defined as P less than or equal to .05.

Results

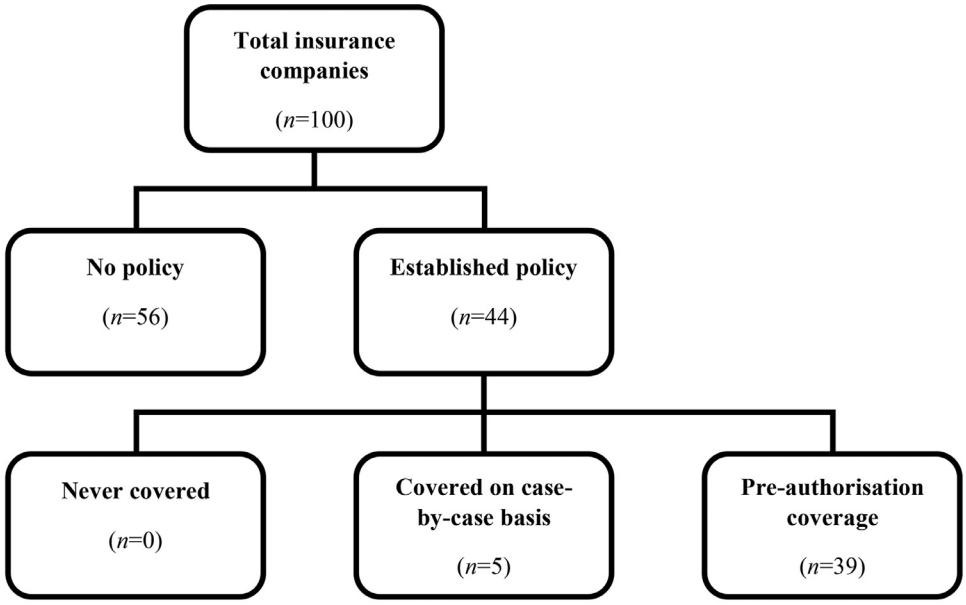
Coverage

One hundred insurance companies were evaluated for the coverage of bilateral or contralateral prophylactic mastectomies for noncancerous indications, including Medicare and Medicaid (Figure 1), where just under half possessed an established policy for PM (44%, n = 44). Most of these policies provided preauthorized coverage (87%, n = 39), whereas 5 (13%) covered on a case-by-case basis. Of the remaining 56 companies who did not possess an established policy, 21 (38%) companies recommended a PM in their genetic screening policy but did not hold a specific PM policy.

Genetic Susceptibility

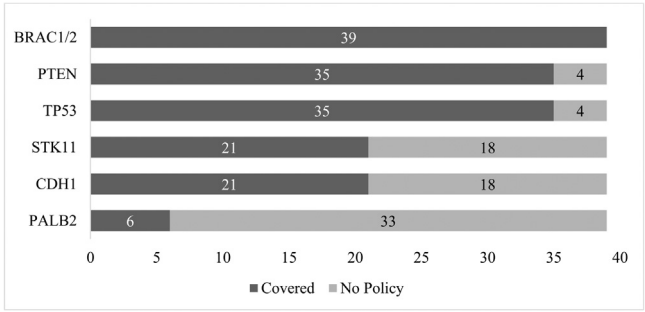
Consistent with SSO, ASBrS, and ASPS recommendations, genetic mutations were covered by all preauthorized policies. Seven mutations were included in policies for the indication of genetic susceptibility (Figure 2). All policies provided PM coverage for patients with a BRCA1 or BRCA2 mutation (100%, n = 39), and a further 6 companies also provided coverage if the mutation was found in an immediate family member (15%). However, 6 (15%) of the policies required confirmation of the high-risk mutation by molecular susceptibility.

Figure 1 Insurance coverage of prophylactic mastectomies.



Never Covered	Case-by-case basis	Pre-authorisation	
	GEHA	Aetna	Geisinger
	Medicaid	Amerihealth	Guidewell
	Pacific Source Health	Arkansas BCBS	Harvard pilgrim
	Plan	Avmed	Hawaii Medical Services
	Tricare	BCBS AL	Healthcare Services Corp
	BCBS NE	BCBS Carefirst	HealthPartners
		BCBS Idaho	Highmark
		BCBS KS	Horizon BCBS NJ
		BCBS MN	Humana
		BCBS NC	Independence BC
		BCBS ND	John Hopkins Healthcare
		BCBS RI	Louisiana Health Service
		BCBS SC	Moda Health
		BCBS VT	Oscar health insurance
		BCBS CA	Lifewise
		Capital Blue Cross	Presbyterian health
		Dean Health Group	Priority Health
		Empire BCBS	University Health
		Fallon Health	Alliance
		Forward Health	UPMC

Figure 2 Presence of genetic mutation as a potential medical necessity criteria for genetic susceptibility.



Certain policies also considered the presence of genetic mutations in family members. For 2 (5%) policies that addressed BRCA1/2 mutations, PM would only be covered if the policy holder's mutation matched a family member's mutation and the family member had an active diagnosis of breast cancer. In addition, 7 insurance policies (18%) also provided coverage if a mutation was present as a syndrome in a first-degree family member: Li-Fraumeni syndrome (TP53 mutation), Cowden syndrome (PTEN mutation), or Bannayan-Riley-Ruvalcaba syndrome (PTEN mutation).

Familial History

Of insurers with an established policy, 37 (95%) provided coverage in the case of a positive family history of breast cancer. ASPS's family history criterion requirements were present in 20 insurance policies (51%), with each criterion summarized in Table 2. SSO's family history criterion was present in 39% of policies (n = 15) and was often proven with a separate risk assessment tool of the provider's choosing, such as the Gail or Claus model, that demonstrated a >20% lifetime risk of developing breast cancer (87%, n = 13) (Table 3). Of those who did not have general family history as a criterion, a further 7 companies (18%) stated they may consider those with an SSO's definition of family history criteria on a case-by-case basis.

Radiation History

Radiation history was defined as any previous radiotherapy for any indication, such as pediatric lymphomas. A history of radiation therapy to the chest, a marker of high-risk patients as recommended by SSO, was an approved indication for PM in 92% of policies (n = 36). In all cases, coverage of PM was dependent on the age of the patient at the time of radiation therapy (Figure 3), with 3 quarters of policies covering if radiation was given between 10 and 30 years old (78%, n = 28).

Personal History of Cancer

Indications for PM based on past malignancy history are summarized in Table 4. For the criteria of a personal, previous history of female breast cancer, a PM for the contralateral breast was authorized in 64% (n = 25) of policies. Whereas in the criteria of ovarian cancer, significantly fewer companies covered a PM compared to previous breast cancer (18% vs. 64%, n = 7, $P < .001$). Of those that did cover a PM in those with ovarian cancer, the majority also required a family history of 1 or more first/second degree relatives to have been diagnosed with breast cancer (86%, n = 6).

Pathological Changes in the Breast

Pathological changes in the breast can describe carcinoma in situ, atypical hyperplasia, mammographic abnormalities of dense breasts, or fibrocystic disease. There are 2 forms of carcinoma in situ of the breast: ductal carcinoma-in-situ (DCIS), a type of breast malignancy, or lobular carcinoma in situ (LCIS), a high risk, nonmalignant lesion. For LCIS, coverage for a PM was provided in most cases (92%, n = 36), where 7 policies (19%) specifically required the diagnosis to be made on biopsy. In contrast, significantly fewer insurance companies provided a preauthorized PM in the setting of DCIS compared to LCIS (n = 2, 6% vs. 92%, $P < .001$) (Table 4).

For atypical hyperplasia, coverage for a PM was provided in 44 % of policies (n = 17). One third-party payer, coverage was explicitly denied in the setting of atypical hyperplasia (3%, *Geisinger*). In settings where lesions could not be biopsied, for example, proximity to skin or chest wall, a PM was covered in two-thirds of the policies (67%, n = 26) (Table 4). Finally, 7 (17%) insurance companies discussed fibrocystic breast disease; the majority (n = 6) denied coverage for a PM Whereas 1 company provided coverage only if the patient was symptomatic and unresponsive to conservative treatment. PM was denied in 5 other specific breast diseases (Table 5).

Discussion

Our data clearly demonstrates the variability in insurance coverage, indications, and medical necessity criteria for a PM. We report a low proportion of insurers (44%) held a clear and publicly available policy for a PM. The benefit of prophylactic mastectomies in reducing breast cancer risk must be taken with great consideration, and for those of significantly high risk.[21] However, the definition of "high risk" is inconsistent among national recommendations and insurance policies. Only 1 medical criterion was universally addressed by the PM policies (BRCA1/2 mutation for genetic susceptibility). Additionally, the definition of family history differed depending on either the ASPS or the SSO definition. Only 1 in 10 policies addressed both possible criteria for family history. If we are

Table 2 Required Criteria for Specific Family History

Reason for Coverage	Number of Companies (n = 39)
Specific family history criteria	20 (51%)
1st degree relative with cancer	
A 1st degree relative with bilateral breast cancer	8 (21%)
A 1st degree relative with breast cancer <50 yo	2 (5%)
A 1st degree relative with breast cancer <45 yo AND another relative with breast cancer	8 (21%)
A 1st degree relative with breast cancer AND another relative with ovarian cancer	7 (18%)
A 1st degree relative with breast cancer AND multiple 2nd/3rd relative with breast cancer	8 (21%)
Multiple 1st degree relatives with breast cancer	7 (18%)
Multiple 1st degree relatives with breast cancer OR ovarian cancer	2 (5%)
1st or 2nd degree relative with cancer	
A 1st/2nd degree relative with multiple primary breast cancers	10 (26%)
A 1st/2nd degree relative with bilateral breast cancers	9 (23%)
3 or more 1st/2nd degree relatives on the same side with breast cancer	9 (23%)
2nd or 3rd degree relative with cancer	
A 2nd/3rd degree relative with breast cancer AND multiple relatives of any degree with ovarian cancer	6 (15%)
Multiple 2nd/3rd degree relatives with breast cancer AND a relative of any degree with ovarian cancer	6 (15%)
Three or more 2nd/3rd degree relatives with breast cancer	7 (18%)
Other	
A 1st degree relative with breast cancer <45yo AND another relative with ovarian cancer	1 (3%)
A relative of any degree with breast cancer AND 2 additional relatives on that side with breast cancer OR ovarian cancer	1 (3%)
A 1st degree relative with breast cancer OR ovarian cancer OR prostate cancer	1 (3%)
Multiple successive generations with breast/ovarian/fallopian tube/prostate/pancreatic/peritoneal cancer	1 (3%)
A 1st degree relative with premenopausal bilateral breast cancer	1 (3%)
Multiple relatives on the same side with cancer, with at least 1 <50yo	1 (3%)
A 1st/2nd degree relative <45yo with breast cancer	1 (3%)
A 1st/2nd degree relative with breast cancer AND a 1st/2nd degree relative with ovarian cancer	1 (3%)
A 1st degree relative with ovarian/fallopian tube/peritoneal cancer AND a 1st/2nd degree relative with breast cancer	1 (3%)
A 1st degree relative with ovarian/fallopian tube/peritoneal cancer AND multiple 3rd degree relatives with breast cancer	1 (3%)

Table 3 Required Criteria for General Family History

Reason for Coverage	Number of Companies (n = 39)
General Family History Criteria	15 (39%)
Covered if > 20% Lifetime risk	*13 (87%)*
Covered in unspecified "Strong Family History"	*2 (13%)*

Figure 3 Medical necessity criteria for the indication of previous radiotherapy.

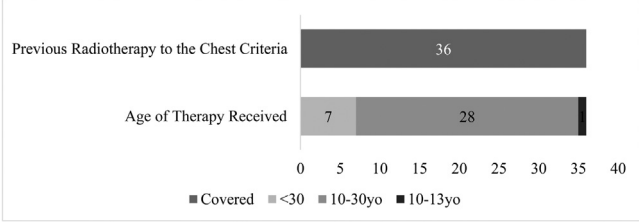


Table 4 Required Medical Necessity Criteria for Personal Medical History of Cancer

Indication for a Prophylactic Mastectomy	Medical Necessity Criteria	Number of Companies (n = 39)
Personal history of malignant neoplasm	History of breast cancer	25 (64%)
	History of ovarian cancer	7 (18%)
Carcinoma in situ of the breast	LCIS	36 (92%)
	DCIS	2 (5%)
Neoplasm of uncertain behavior of the breast	Atypical hyperplasia	17 (44%)
	Mammographic abnormalities not amenable to biopsy	26 (67%)
Fibrocystic breast disease	Symptomatic and unresponsive to conservative treatment	1 (3%)

Abbreviations: DCIS = ductal carcinoma in situ; LCIS = lobular carcinoma in situ.

Table 5 Denied Indications for Prophylactic Mastectomy

Denied Indication	Number of Companies (n = 39)
Atypical hyperplasia	1 (3%)
Fibrocystic breast disease	6 (15%)
Diabetic mastopathy	3 (8%)
Pseudoangiomatous stromal hyperplasia (PASH)	3 (8%)
Uncontrolled inflammatory breast disease (ie, chronic mastitis or macrocystic disease)	1 (3%)

to address the complex decision for a PM, we require greater availability and flexibility in policies of US insurance companies.

We report that genetic mutations were covered by all preauthorized policies. This universal coverage reflects the global agreement between SSO, ASBrS, and ASPS; these societies advocate for PM in patients with genetic susceptibility. Patients with a BRCA1 or BRCA2 mutation have a 60% to 90% lifetime risk of developing breast cancer[3] and PMs have been documented to reduce risk by >90%.[21,22] However, the utility of PMs in this population have since been put into question, as it may be comparable to other nonoperative measures.[23] Nonetheless, since the discovery of the association between BRCA genes and breast cancer, numerous other genes have also come to light to potentially increasing lifetime risk of breast cancer.[4,24,25] Examples such as TP53 and PTEN can carry a lifetime risk comparable to that of BRCA1/2[11] and are present in 90% of insurance policies. Others, such as CDH1 and STK11, can also provide a notable lifetime risk of 35% to 50%,[11] and is reflected in 54% of approval policies. When reflecting on the array of genetic results which may confer an increased breast cancer risk, the National Comprehensive Cancer Network (NCCN) has compiled a comprehensive review of their management.[26,27] For CDH1 and STK11, the evidence for risk-reducing mastectomies was deemed "insufficient" and must be considered with the patient's family history.[26] Even in higher risk genes, such as TP53, PTEN, and even BRCA1/2, PMs should only be discussed in comprehensive counselling, and considered with other risk-reducing options such a regular screening and chemoprevention.[26,27]

We also report significant variability in the assessment of family history between the insurance policies, with multiple potential definitions of a high-risk family history. For those that reflect the ASPS definition of family history criteria, the source of these criteria appears inconsistent. One potential source is a set of criteria created by Hartmann et al.[28] , who produced a retrospective study highlighting the efficacy of PMs in their population. This outlines 8 specific criteria that may classify a patient as high-risk (Table 6), and this was the most adopted framework from our cohort of polices. However, this still only represented 16% of those who assessed family history. The remaining policies took an amalgamated approach to their selection criteria, with little overlap or consistency between them, which in turn may cause more confusion than clarity for the patient.

Though the scientific reasoning for ASPS's definition of familial history is vague, the current literature to support SSO's definition is much more concrete. This is where familial risk may not be best defined by a single situation, but rather a more global assessment of cancer risk is required, 1 that is supported by NCCN guidelines as well.[26,27,29] This can be achieved by using a risk assessment tool to calculate lifetime risk, such as the Gail or Claus model.[2,6] However, these come with their own drawbacks. Many are situation-specific or based on a subset of the population that cannot be generalized to the public. For example, the Gail model was based off an entirely white-Caucasian cohort. Since then, newer models have been produced to be more representative of the population, but they require more rigorous evaluation.[2] Thus, with so many potential assessments of familial risk, we require greater flexibility of options within our insurance criteria, as opposed to inconsistent limitations.

The use of external radiation is another risk factor for the development of breast cancer,[30] and this is particularly true in radiation therapy for childhood cancers, such as Hodgkin lymphoma.[31] Their lifetime risk of breast cancer development can be comparable to that of BRCA positive mutations.[32] Of note, the increased risk has been noted in any pediatric age of diagnosis and radiation therapy.[33,34] Thus, it is unsurprising that almost all insurance policies included prior radiation as a covered indication for PM. Additionally, the national societies (SSO, ASBrS, and ASPS) recommend PM in the setting of previous radiation.[11-13] There is a significant increased risk in breast malignancy if the radiation was received earlier than

Table 6 High-Risk Criteria for Recommendation of a Prophylactic Mastectomy by Hartmann et al[23]

• Two or more first-degree relatives with breast cancer
• One first-degree relative and 2 or more second-degree or third-degree relatives with breast cancer
• One first-degree relative with breast cancer before the age of 45 and 1 other relative with breast cancer
• One first-degree relative and 1 or more relatives with ovarian cancer
• Two or more second-degree or third-degree relatives with breast cancer and 1 or more relatives with ovarian cancer
• One second-degree or third-degree relatives with breast cancer and 2 or more relatives with ovarian cancer
• Three or more second-degree or third-degree relatives with breast cancer
• One first-degree relative with bilateral breast cancer

age 30, with the risk highest if received at an early age. However, the majority of insurers required the prior radiotherapy to have occurred between the ages 10 and 30. These age restrictions may create unnecessary barriers for patients who may want to discuss a PM as a potential risk-reducing method for breast cancer.

Almost two-thirds of insurance companies surveyed would cover a contralateral mastectomy if there was a personal history of cancer. Contralateral PM is commonly considered in patients with an existing diagnosis of unilateral breast cancer. Since their initial use in BRCA positive patients, there was an increase in breast cancer patients requesting a PM in the contralateral nonaffected breast, with the aim to reduce the incidence of contralateral breast cancer.[8] However, the utility of PMs in this patient cohort has been debated, as without a significant familial history or high risk diagnosis (such as diagnosed <45 years old or bilateral breast cancer), the patient may not have an increase in life expectancy afterwards.[10,18] In fact, ASBrS recommends PM in high risk but unaffected patients but discourages contralateral PM in those without increased risk and unilateral breast cancer. This discordance between national recommendations may account for the observed variability in insurance coverage.[12] Although it is unclear whether breast cancer alone is indicative of an increased risk of contralateral breast cancer, some benign breast disease can act as high-risk lesions in the affected breast. LCIS, atypical hyperplasia and high mammographic breast density have each shown to be independent risk factors for developing breast cancer.[5,35,36] Though these patients have been shown to potentially benefit from PMs,[5,37] there is growing support that similar levels of risk-reduction can be achieved with high risk screening and potential chemoprevention, such as via tamoxifen.[26,27] Strikingly, significantly fewer companies covered PM in the setting of DCIS compared to LCIS. It is possible that DCIS is included in the definition of personal history of malignant neoplasm and patients receive coverage for PM via this avenue. In the case of fibrocystic disease, it does not possess the same significant increased risk of breast cancer, and thus, a PM is explicitly not recommended.[38] Although suggested as an indication by ASPS, it is largely not accounted for by insurance companies, and when it is, it is typically denied. Thus, for noncancerous breast disease, the utility of a PM must be taken with care and with a multidisciplinary specialist team to consider the wider literature on their benefits.

The limitations of this article lie in its cross-sectional nature. Due to the wide variety of medical plans and the ongoing updates to them, the data and recommendations may not be applicable to all cases. As the lack of accessible policy and case-by-case scenarios are assessed on an individual basis, our estimations could be over- or under-representative of true insurance coverage. This article also assesses the ease of which a patient can access coverage for a PM, but does not address the complex, multifaceted decision making required to decide if a PM is the most appropriate course of action. However, that conversation cannot begin if there is no PM insurance policy, or it is denied in the first place. Further studies could assess how well patients are able to access the tools required to fulfil the pre-requisite criteria, such as genetic testing. Nonetheless, the strength in out paper lies in the large number of companies assessed, and how the authors are the first to thoroughly assess and categorizes the complex criteria required from third-party payers for a PM.

Conclusion

In this paper, we have provided a comprehensive report of the variety of indications and criteria required for a PM. There is a marked level of variability in the insurance policies of prophylactic mastectomies, in both their indications and medical necessity criteria. The decision to undergo a PM must be carefully considered with a patient's caring team, and not be affected by the coverage of their insurers. As a PM is a sensitive, complex decision-making process, we highlight the different influences insurance companies may have in this life-altering choice.

Clinical Practice Points

- A patient's access to private medical insurance can be a predictive factor in the likelihood to receive a Prophylactic Mastectomy (PM).
- Significant variability in insurance coverage between companies can lead to further inequalities in access to this procedure. The authors have previously discussed the variability in coverage of

contralateral prophylactic mastectomies in the setting of a breast cancer diagnosis.

- In this study, the authors evaluate the current landscape of insurance coverage for bilateral or contralateral prophylactic mastectomies in noncancerous or "high-risk" patients. Preauthorized coverage of PMs was provided by 39% of insurance policies (n = 39). While there was consensus amongst these policies to cover a PM for BRCA1/2 mutations (n = 39, 100%), other indications had more variable coverage such as previous radiotherapy (92%), pathological changes in the breast (3%–92%), personal history of cancer (64%) and family history risk factors (39%–51%).
- This study highlights the influence that insurance companies may have in this life-altering choice. Physicians and patients alike should advocate for fair and equal access to PM for certain clinical indications.

Disclosure

The authors have stated that they have no conflicts of interest.

Human Studies and Subjects

Not applicable.

Acknowledgments

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

References

1. National Cancer Institute. Surveillance, Epidemiology, and End Results Program. Accessed 12 November 2020. Available at:https://seer.cancer.gov/
2. Moorthie S, Gaynor L, Burton H, Hall A, Kroese M, Raza S. Personalised prevention in breast cancer the policy landscape 2 personalised prevention in breast cancer: the policy landscape. Accessed 13 November 2020. Available at:www.b-cast.eu; 2017.
3. Greene MH. Genetics of breast cancer. *Mayo Clin Proc*. 1997;72:54–65. doi:10.4065/72.1.54.
4. Angeli D, Salvi S, Tedaldi G. Genetic predisposition to breast and ovarian cancers: how many and which genes to test? *Int J Mol Sci*. 2020;21. doi:10.3390/ijms21031128.
5. Hartmann LC, Sellers TA, Frost MH, et al. Benign breast disease and the risk of breast cancer. *N Engl J Med*. 2005;353:229–237. doi:10.1056/nejmoa044383.
6. Pashayan N, Antoniou AC, Ivanus U, et al. Personalized early detection and prevention of breast cancer: ENVISION consensus statement. *Nat Rev Clin Oncol*. 2020;17:687–705. doi:10.1038/s41571-020-0388-9.
7. Jakub JW, Peled AW, Gray RJ, et al. Oncologic safety of prophylactic nipple-sparing mastectomy in a population with BRCA mutations: a multi-institutional study. *JAMA Surg*. 2018;153:123–129. doi:10.1001/jamasurg.2017.3422.
8. McDonnell SK, Schaid DJ, Myers JL, et al. Efficacy of contralateral prophylactic mastectomy in women with a personal and family history of breast cancer. *J Clin Oncol*. 2001;19:3938–3943. doi:10.1200/JCO.2001.19.19.3938.
9. Stefanek M, Hartmann L, Nelson W. Risk-reduction mastectomy: clinical issues and research needs. *J Natl Cancer Inst*. 2001;93:1297–1306. doi:10.1093/jnci/93.17.1297.
10. Fayanju OM, Stoll CRT, Fowler S, et al. Contralateral prophylactic mastectomy after unilateral breast cancer: a systematic review and meta-analysis. *Ann Surg*. 2014;260:1000–1010. doi:10.1097/SLA.0000000000000769.
11. Hunt KK, Euhus DM, Boughey JC, et al. Society of surgical oncology breast disease working group statement on prophylactic (risk-reducing) mastectomy. *Oncol*. 2017;24:375–397. doi:10.1245/s10434-016-5688-z.
12. Boughey JC, Attai DJ, Chen SL, et al. Contralateral Prophylactic Mastectomy (CPM) consensus statement from the American Society of Breast Surgeons: data on CPM outcomes and risks. *Ann Surg Onc*. 2016;23:3100–3105. doi:10.1245/s10434-016-5443-5.
13. American Society of Plastic Surgeons. ASPS recommended insurance coverage criteria for third-party payers: reconstruction after prophylactic mastectomy. Accessed 5 August 2022. Available at:https://www.plasticsurgery.org/documents/Health-Policy/Reimbursement/insurance-2017-prophylactic-mastectomy.pdf; 2019:1-6.
14. Arrington AK, Jarosek SL, Virnig BA, et al. Patient and surgeon characteristics associated with increased use of contralateral prophylactic mastectomy in patients with breast cancer. *Ann Surg Oncol*. 2009;16:2697–2704. doi:10.1245/s10434-009-0641-z.
15. Jerome-D'emilia B, Trinh H. Socioeconomic factors associated with the receipt of contralateral prophylactic mastectomy in women with breast cancer. *J Women's Heal*. 2020;29:220–229. doi:10.1089/jwh.2018.7350.
16. Gebran SG, Knighton B, Ngaage LM, et al. Insurance coverage criteria for bariatric surgery: a survey of policies. *Obes Surg*. 2020;30. doi:10.1007/s11695-019-04243-2.
17. Ngaage LM, Knighton BJ, McGlone KL, et al. Health insurance coverage of gender-affirming top surgery in the United States. *Plast Reconstr Surg*. 2019;144:824–833. doi:10.1097/PRS.0000000000006012.
18. Ha M, Ngaage LM, Klein M, et al. Contralateral prophylactic mastectomy in the setting of breast cancer diagnosis and their insurance coverage in the United States. *Breast J*. 2021 Epub ahead of print. PMID:34528334 . doi:10.1111/tbj.14280.
19. Henry J. Kaiser Foundation. Market share and enrollment of largest three insurers – individual market | KFF. Accessed 15 November 2020. Available at: https://www.kff.org/private-insurance/state-indicator/market-share-and-enrollment-of-largest-three-insurers-individual-market/?currentTimeframe=1&selectedRows=%7B%22states%22:%7B%22all%22:%7B%7D%7D,%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%7D&sortMod
20. National Association of Insurance Commissioners. 2017 market share reports for the top 125 accident and health insurance groups and companies by state and countrywide. Accessed 15 November 2020. Available at:https://www.naic.org/prod_serv/MSR-HB-18.pdf
21. Carbine NE, Lostumbo L, Wallace J, et al. Risk-reducing mastectomy for the prevention of primary breast cancer. *Cochrane Database Syst Rev*. 2018;2018. doi:10.1002/14651858.CD002748.pub4.
22. Rebbeck TR, Friebel T, Lynch HT, et al. Bilateral prophylactic mastectomy reduces breast cancer risk in BRCA1 and BRCA2 mutation carriers: the PROSE study group. *J Clin Oncol*. 2004;22:1055–1062. doi:10.1200/JCO.2004.04.188.
23. Terribile DA, Mason EJ, Murando F, et al. Surgical management of BRCA pathogenic variant carriers with breast cancer: a recent literature review and current state of the art. *Minerva Surg*. 2021. doi:10.23736/S2724-5691.21.09009-2.
24. De Jong MM, Nolte IM, Te Meerman GJ, et al. Genes other than BRCA1 and BRCA2 involved in breast cancer susceptibility. *J Med Genet*. 2002;39:225–242. doi:10.1136/jmg.39.4.225.
25. Hrabincová SE. Recommendations for preventive care for women with rare genetic cause of breast and ovarian cancer. *Klin Onkol*. 2019;32:2–6. doi:10.14735/amko2019S6.
26. NCCN clinical practice guidelines in oncology (NCCN Guidelines) genetic/familial high-risk assessment: breast and ovarian. Version 3.2019 Jan 18, 2019. Available at: Available at:https://www2.tri-kobe.org/nccn/guideline/gynecological/english/genetic_familial.pdf Accessed January 5, 2021.
27. Daly MB, Pilarski R, Yurgelun MB, et al. NCCN guidelines insights: genetic/familial high-risk assessment: breast, ovarian, and pancreatic, version 1.2020: featured updates to the NCCN guidelines. *J Natl Compr Canc Netw*. 2020;18:380–391. doi:10.6004/jnccn.2020.0017.
28. Hartmann LC, Schaid DJ, Woods JE, et al. Efficacy of bilateral prophylactic mastectomy in women with a family history of breast cancer. *N Engl J Med*. 1999;340:77–84. doi:10.1056/NEJM199901143400201.
29. NICE GuidelinesFamilial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer. *NCBI Bookshelf*. 2019. PublishedAvailable at:. https://www-ncbi-nlm-nih-gov.proxy-hs.researchport.umd.edu/books/NBK552606/ .
30. Linet MS, Slovis TL, Miller DL, et al. Cancer risks associated with external radiation from diagnostic imaging procedures. *CA Cancer J Clin*. 2012;62:75–100. doi:10.3322/caac.21132.
31. Kenney LB, Yasui Y, Inskip PD, et al. Breast cancer after childhood cancer: a report from the Childhood Cancer Survivor Study. *Ann Intern Med*. 2004;141:590–597. doi:10.7326/0003-4819-141-8-200410190-00006.
32. Boucher AA, Blaes AH. Prophylactic mastectomy: a treatment alternative for Hodgkin survivors? *Clin Breast Cancer*. 2013;13:307–308. doi:10.1016/j.clbc.2013.06.001.
33. Bhatia S, Yasui Y, Robison LL, et al. High risk of subsequent neoplasms continues with extended follow-up of childhood Hodgkin's disease: report from the Late Effects Study Group. *J Clin Oncol*. 2003;21:4386–4394. doi:10.1200/JCO.2003.11.059.
34. Moskowitz CS, Chou JF, Wolden SL, et al. Breast cancer after chest radiation therapy for childhood cancer. *J Clin Oncol*. 2014;32:2217–2223. doi:10.1200/JCO.2013.54.4601.
35. Connolly JL, Schnitt SJ. Benign breast disease resolved and unresolved issues. *Cancer*. 1993;71:1187–1189. doi:10.1002/1097-0142(19930215)71:4<1187::AID-CNCR2820710402>3.0.CO;2-V.
36. Ghosh K, Vachon CM, Pankratz VS, et al. Independent association of lobular involution and mammographic breast density with breast cancer risk. *J Natl Cancer Inst*. 2010;102:1716–1723. doi:10.1093/jnci/djq414.
37. Geiger AM, Yu O, Herrinton LJ, et al. A population-based study of bilateral prophylactic mastectomy efficacy in women at elevated risk for breast cancer in community practices. *Arch Intern Med*. 2005;165:516–520. doi:10.1001/archinte.165.5.516.
38. Tice JA, O'Meara ES, Weaver DL, et al. Benign breast disease, mammographic breast density, and the risk of breast cancer. *J Natl Cancer Inst*. 2013;105:1043–1049. doi:10.1093/jnci/djt124.