Eligibility criteria in private and public coverage policies for *BRCA* genetic testing and genetic counseling

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Purpose: Coverage policies for genetic services for hereditary cancers are of interest because the services influence cancer risk reduction for both persons with cancer and their family members. We compared coverage policies for *BRCA* genetic testing and genetic counseling among selected payers in the United States to illuminate eligibility criteria variation that may explain differential access by insurance type. We compared these policies with policies for breast cancer screening with magnetic resonance imaging to consider whether payers apply a unique policy approach to genetic services. **Methods:** We conducted a case study of large private and public payers selected on number of covered lives. We examined coverage policies for *BRCA* genetic testing, genetic counseling, and screening with magnetic resonance imaging and the eligibility criteria for each. We compared eligibility criteria against National Comprehensive Cancer Network guidelines. **Results:** Eligibility criteria for *BRCA* testing were related to personal history and family history of cancer. Although private payers covered *BRCA* testing for persons with and without cancer, the local Medicare carrier in our study only covered testing for persons with cancer. In contrast, Arizona's Medicaid program did not cover *BRCA* testing. Few payers had detailed eligibility criteria for genetic counseling. Private payers have more detailed coverage policies for both genetic services and screening with magnetic resonance imaging in comparison with public payers. **Conclusion:** Despite clinical guidelines establishing standards for *BRCA* testing, we found differences in coverage policies particularly between private and public payers. Future research and policy discussions can consider how differences in private and public payer policies influence access to genetic technologies and health outcomes. ***Genet Med* 2011: 13(12):1045–1050.**

Key Words: *BRCA testing, coverage policy, family history, genetic counseling, hereditary breast and ovarian cancer, payer*

BRCA testing is one of the first genetic tests to move from bench to bedside. Several professional associations have included *BRCA* testing in clinical guidelines to identify patients at high risk for hereditary breast and ovarian cancer.[1–5] Guidelines from the US Preventive Services Task Force (USPSTF) recommend genetic counseling and *BRCA* testing for "… women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes."[2] In addition, the National Comprehensive Cancer Network (NCCN) lays out in detail a clinical pathway to help providers identify persons with hereditary breast and ovarian cancer.[4] NCCN has also incorporated into its guidelines American Cancer Society recommendations for breast cancer screening using magnetic resonance imaging (MRI) for persons at high risk for breast cancer[6] (Table 1).

Access to *BRCA* testing and related services often depends on cost and coverage of services by payers.[7–9] To leverage value of technologies and services, payers define scope of healthcare benefits based on eligibility criteria. Previous researchers have discussed coverage policy development and have even discussed policy formulation and considerations for genetic testing specifically.[10–15] Although researchers have described policy development processes, few studies have examined the coverage policies themselves. Recently, Latchaw et al.[16] reviewed policies of 10 private payers in Illinois and observed wide variability in coverage.

Coverage policies "… influence[s] the types of medical care Americans receive, because health insurance coverage is the gateway to the availability of medical innovations."[17] Policies contribute to setting thresholds of whom to test, then which screening and prevention services to offer and when. Without an understanding of the composition and content of the policies, we cannot begin to hypothesize how criteria within the policies may affect access by covered populations or differences in access between payers. Coverage policies for genetic services for hereditary cancers are of particular interest because the services influence cancer risk reduction for both persons with cancer and their family members.

We build on prior research by studying several national and local coverage policies for public and private payers to determine and compare the criteria included in coverage policies for *BRCA* genetic testing and genetic counseling. We also assess policies for a comparison service, breast cancer screening with MRI, to consider whether payers apply a unique policy approach to genetic testing and genetic counseling in relationship to other services. This article (1) describes the eligibility criteria for cancer risk genetic counseling, *BRCA* testing, and breast cancer screening with MRI; (2) compares eligibility criteria between payers and between services; and (3) discusses implications of these policies for covered persons.

MATERIALS AND METHODS

We conducted a case study of selected private and public payers. We chose payers and states with the largest number of covered lives because coverage policies would potentially have an impact on a large number of people. Number of covered lives is estimated by the Health Care Delivery Policy Program at Harvard University and the Kaiser Family Foundation.[18–20] We selected states with a higher than average number of beneficiaries in 2007 (Medicaid) and 2010 (Medicare). In total, we reviewed policies from eight private payers and 17 states.

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Table 1 National Comprehensive Cancer Network (NCCN) clinical guidelines

NCCN recommends *BRCA* testing for the following people:

Individuals from a family with a known *BRCA* mutation;

OR

Individuals with a personal history of breast cancer and:

- Diagnosed age ≤45 yr
- Diagnosed age ≤50 yr with ≥1 close blood relative with breast cancer ≤50 yr and/or ≥1 close blood relative with epithelial ovarian/fallopian tube/primary peritoneal cancer at any age
- Two breast primaries when first breast cancer diagnosis occurred before age 50 yr
- Diagnosed age <60 yr with a triple negative breast cancer
- Diagnosed age <50 yr with a limited family history
- Diagnosed at any age, with ≥2 close blood relative with breast and/or epithelial ovarian/fallopian tube/primary peritoneal cancer at any age
- Close male blood relative with breast cancer
- Personal history of epithelial ovarian/fallopian tube/primary peritoneal cancer
- Ethnicity associated with higher mutation frequency (eg, Ashkenazi Jewish)

OR

Individuals with a personal history of epithelial ovarian/fallopian tube/primary peritoneal cancer;

OR

Individuals with a personal history of male breast cancer;

OR

Individuals with a personal history of breast and/or ovarian cancer at any age with ≥2 close blood relatives with pancreatic cancer at any age

OR

Individuals with a personal history of pancreatic cancer at any age with ≥2 close blood relatives with breast and/or ovarian cancer and/or pancreatic cancer at any age

OR

Individuals whose family history of cancer reflect:

- First- or second-degree blood relative meeting any of the above criteria
- Third-degree blood relative with breast cancer and/or ovarian/fallopian tube/primary peritoneal cancer with ≥2 close blood relatives with breast cancer (at least one with breast cancer ≤50 yr) and/or ovarian cancer

NCCN recommends annual breast cancer screening with MRI as an adjunct to mammography for the following people:

Individuals with a *BRCA* mutation;

OR

First-degree, untested relatives of *BRCA* carriers;

OR

Individuals with a lifetime breast/ovarian cancer risk of 20% or greater as defined by BRCAPRO or other models based on family history; OR

Carrier or family history of mutation in *TP53* or *PTEN*;

OR

Radiation to the chest between ages 10 and 30 years

Sources: National Comprehensive Cancer Network. Genetic/familial high-risk assessment: breast and ovarian, version 1, 2011. Practice guidelines. Available at: http://www.nccn.org. Accessed May 12, 2011.
National Comprehensive Cancer Network. Breast cancer screening and diagnosis, version 1, 2011. Practice guidelines. Available at: http://www.nccn.org. Accessed May 12, 2011.

We searched several online databases in May 2011 to identify *BRCA* genetic testing and genetic counseling coverage policies among the selected payers. These included private payer websites, state Medicaid sites, the Medicare coverage policy database, and other electronic databases such as PubMed, Lexis Nexis legal, and Google.[21–28]

We identified *BRCA* testing and genetic counseling coverage policies for four private payers (Aetna, Cigna, Humana, and UnitedHealthcare) representing more than 50 million covered lives. We identified one local Medicare carrier (Washington State) with a policy addressing *BRCA* testing. We also found statements from four Medicaid programs (AZ, CA, IL, and NY)[29–39] (Table 2). We then identified coverage policies for breast cancer screening with MRI among these payers.[40–43]

We used the NCCN clinical guidelines as a framework for examining eligibility criteria. We categorized criteria based on personal history of breast or ovarian cancer; family history of breast or ovarian cancer; race/ethnicity; age at diagnosis; *BRCA* mutation carrier status, family member carries a *BRCA* mutation, and/or other criteria.

RESULTS

Genetic testing

Personal history of cancer is a primary criterion for coverage among both private and public payers. Private payers, the local Medicare carrier, and California Medicaid combine this criterion with additional secondary criteria such as young age at diagnosis, family history, family history of *BRCA* carriers, or ethnicity (e.g., founder populations of Ashkenazi Jewish, Icelandic, Swedish, Hungarian, or other). Two private payers include clauses related to limited family structure or adoption of children.

Family history of breast and ovarian cancer is a primary criterion for coverage eligibility but only among private payers and California Medicaid. In contrast, Washington State's local Medicare coverage determination indicates that family history without a personal history of cancer is not adequate for Medicare coverage. The policy states, "Screening services, such as presymptomatic genetic tests and services, are those used to detect an undiagnosed disease or disease predisposition, and as such are not a Medicare benefit and not covered by Medicare. Similarly, Medicare may not reimburse the costs of tests/examinations that assess the risk for and/or of a condition unless the risk assessment clearly and directly effects the management of the patient …"[37]

Finally, documents from state Medicaid programs range from decisions of noncoverage to policies without eligibility criteria. Arizona's policy states that "Genetic testing is not covered to

Table 2 Eligibility criteria within *BRCA* testing coverage policies, by payer[a]

			Private payers					Medicaid			
Criterion 1	AND criterion 2	AND criterion 3	United	Humana	Aetna	Cigna	Medicare LCD WA	AZ	CA	IL	NY
Personal hx	Age <45 y		●	●	●	●	●		●		
	Age <50 y			●					●		
		Family hx	●	●	●	●					
		Limited family or adopted	●		●						
	Family hx		●	●	●	●	●		●		
	Ethnicity		●	●	●	●	●		●		
	Relative		●		●		●				
Family hx			●	●	●	●			●		
	Age of relative		●						●		
	Ethnicity		●	●					●		
	Relative								●		
Relative			●	●	●	●					
Other					Risk tool gives 10% probability of mutation		To manage patient; Informed consent for post-test counseling; Laboratory meets ASCO recommendations	Noncovered service		Covered; no eligibility criteria identified	Covered; necessary information accompanies claims

Solid circles indicate that the coverage policy of the payer (column) includes the eligibility criterion (row).

[a]The layers of criteria within some coverage policies. Criterion 1 represents the broadest category of requirements. Criterion 2 and criterion 3 may be added as additional requirements. For example, united will cover *BRCA* testing for a person with a personal history of cancer (criterion 1) who was diagnosed before the age of 50 yr (criterion 2) AND who has a family history of breast/ovarian cancer (criterion 3).

Age <40 yr, diagnosed with cancer at an age younger than 40 yr; age <50 yr, diagnosed with cancer at an age younger than 50 yr; ASCO, American Society of Clinical Oncology; ethnicity, founder populations of Ashkenazi Jewish, Icelandic, Swedish, Hungarian or other; family hx, family history of breast or ovarian cancer; LCD, local coverage determination; limited family, two or fewer first- or second-degree female relatives in the same lineage that lived to age 45; Personal hx, personal history of breast or ovarian cancer; relative, a family member carries *BRCA* mutation.

determine whether a member carries a hereditary predisposition to cancer or other diseases. Genetic testing is also not covered for members diagnosed with cancer to determine whether their particular cancer is due to a hereditary genetic mutation known to increase the risks of developing that cancer."[31] Memos, policy manuals, and fee schedules indicate that Illinois and New York Medicaid programs cover *BRCA* testing, but we did not identify any specific eligibility criteria from these payers.

Genetic counseling

Private payers have coverage policies for genetic counseling but do not outline in depth the eligibility criteria for receiving this service. All four private payers refer to genetic counseling services in relationship to receiving genetic testing or guiding treatment. Medicare in Washington also covers counseling before and after genetic testing. We did not identify policies for genetic counseling for the Medicaid programs in this study (Table 3).

Breast cancer screening with MRI

Private payers cover breast cancer screening with MRI for persons at high risk for hereditary breast and ovarian cancer. The eligibility criteria within private payer policies largely reflect NCCN guidelines (Table 4). Although we identified no policies specific to breast cancer screening with MRI for the public payers, Illinois and New York have considered legislation mandating coverage of screening by all insurers within the state.[44,45]

DISCUSSION

Our example of *BRCA* testing and genetic counseling highlights differences in coverage policies between four private and five public payers that may affect access and outcomes, particularly among enrollees with public insurance.

Private payers' policies are similar in content and include coverage for those with a personal history of cancer or a family history of cancer. In the absence of coverage for genetic counseling, primary care or other providers may have responsibility for taking and documenting family history. This may affect eligibility for coverage of testing as medical providers do not always take reliable family histories.[46–51] Requirements for documentation of family history may also have an impact on access among persons who cannot obtain family history due to blocked family communications, dispersed families, or differing concepts of cancer and family relations.[52–54]

The local Medicare policy (first implemented in 2007) that we reviewed covers only persons with a personal history of cancer despite USPSTF recommendations to test women with a family history of cancer.[2,55] Future studies can document whether *BRCA* testing coverage changes among public payers in response to passage of the Patient Protection and Affordable Care Act. This new law eliminates cost sharing for preventive services recommended by the USPSTF.[56]

Several Medicaid programs in our study have policies with no eligibility criteria or consider *BRCA* testing a noncovered service. It is unclear what lack of defined criteria may mean for persons seeking *BRCA* testing or genetic counseling in a public payer setting. One possibility is inconsistent coverage determinations that occur on a case-by-case basis. Alternatively, lack of defined criteria may result in a lower threshold that must be met before receiving coverage. These differences may have implications for access among low-income persons and for regional variations in utilization.

Table 3 Eligibility criteria within coverage policies for genetic counseling for disease risk, by payer

Private payers				Medicare LCD	Medicaid			
United	Humana	Aetna	Cigna	WA	AZ	CA	IL	NY
Conducted before and after genetic testing	Conducted by a physician or certified genetic counselor; Clinically valid test is available; Test impacts treatment, is for the number of genes to establish diagnosis, is allowed once during lifetime per disease.	Authorized by primary care physician; Provided with genetic testing and American College of Medical Genetics guidelines	Pre- and posttest genetic counseling with a physician or a licensed or certified genetic counselor for an individual recommended for covered genetic testing	Conducted by a qualified and trained practitioner	No policy identified	No policy identified	Service is covered, but no eligibility criteria were identified	No policy identified

LCD, local coverage determination.

Table 4 Eligibility within coverage policies for breast cancer screening with MRI

	Private payers				Medicare	Medicaid			
Criterion	United	Humana	Aetna	Cigna	WA	AZ	CA	IL	NY
BRCA+	●	●	●	●					
Relative	●	●	●	●					
Model	●	●	●	●					
TP53/*PTEN*	●	●	●	●					
Radiation	●	●	●	●					
Other	Male relative with breast cancer;				No policy identified	No policy identified	No policy identified	No policy identified[a]	No policy identified[a]
	Relatives with either 2 breast cancers or breast and ovarian cancer;								
	Two or more first-degree relatives with breast cancer;								
	Family history of breast or ovarian cancer and Ashkenazi Jewish background								

Solid circles indicate that the coverage policy of the payer (column) includes the eligibility criterion (row).
[a]These states have considered legislation mandating coverage of breast cancer screening with MRI. At the time of the study, none of the bills had passed.
BRCA+, individuals with a *BRCA* mutation; relative, first-degree, untested relatives of *BRCA* carriers; model, individuals with a lifetime breast/ovarian cancer risk of 20% or greater as defined by BRCAPRO or other models based on family history; radiation, radiation to the chest between ages 10 and 30 years; *TP53/PTEN*, carrier or family history of mutation in *TP53* or *PTEN*.

We compared policies for *BRCA* testing with policies for screening with MRI. Private payers included detailed eligibility criteria for both *BRCA* testing and MRI, whereas coverage policies from public payers were largely absent. This suggests that private payers may communicate policies and eligibility criteria more explicitly than public payers, and private payers' open approach may not be unique to genetic testing.

The scope of this assessment is limited to only a convenience sample of payers and policies. The large plans in this analysis may have a more developed system for reviewing evidence and updating coverage policies compared with smaller plans. These large payers, however, may act as trendsetters with smaller payers adopting similar policies based on the large payers' evidence reviews and policies. Although we include a limited number of plans, they cover approximately 50 million privately insured lives, 1.5 million lives under a local Medicare carrier, and 18.7 million lives under four state Medicaid programs. This research represents the state of coverage in 2011, but policies change over time. As a result, the policies that we identify may not be those used by the payers to determine coverage. Also, importantly, a lack of policy does not equal lack of coverage; furthermore, the presence of a policy is not synonymous with coverage.[57]

This analysis highlights how even an established genetic technology for a hereditary condition continues to manifest in differential coverage policies. Importantly, we suggest open discussions between policy makers, patients, advocates, and researchers regarding the coverage of genetic technologies among public payers in particular. Within a context of severe state budget constraints, we must continue to evaluate the need for genetic testing in tandem with coverage priorities for other important preventive health services that extend access to a broader segment of the population.

In summary, coverage policies among private and public payers vary despite professional guidelines that establish *BRCA* testing as standard of care. Policies range from *BRCA* testing as a noncovered service to policies with detailed eligibility criteria emphasizing personal history and family history of cancer. Future research and policy discussions can consider how policies affect access and utilization of services among privately insured compared with publicly insured populations. In the future, the Patient Protection and Affordable Care Act may affect coverage policies for *BRCA* testing and genetic counseling among public payers.

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