Oregon Cancer Genomics Surveillance Program

Health Insurance Coverage of Cancer Genetic Services in Oregon

Survey Results Report

Survey Research Lab

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Acronyms

ACMG	American College of Medical Genetics
ACOG	American Congress of Obstetricians and Gynecologists
ACR	American College of Radiology
ACS	American Cancer Society
AGA	American Gastroenterological Association
AHRQ	Agency for Healthcare Research and Quality
ASBS	American Society of Breast Surgeons
ASCO	American Society of Clinical Oncology
ASCRS	American Society of Colon and Rectal Surgeons
ASHG	American Society of Human Genetics
ASPS	American Society of Plastic Surgeons
BART	BRACAnalysis® Rearrangement Test
BRCA	Breast Cancer Susceptibility Gene 1 and/or 2
EGAPP	Evaluation of Genomic Applications in Practice and Prevention
FOBT	Fecal Occult Blood Test
ISCI	Institute for Clinical Systems Improvement
LCD	Local Coverage Decision
MMR	Mismatch Repair Gene
NACHGR	National Advisory Council for Human Genome Research
NBCC	National Breast Cancer Coalition
NCCN	National Comprehensive Cancer Network
NCI	National Cancer Institute
NGC	National Guideline Clearinghouse
NHCTF	National Hereditary Cancer Task Force
NICE	National Institute for Health and Clinical Excellence
NSGC	National Society of Genetic Counselors
SBI/ACR	Society of Breast Imaging/American College of Radiology
SGO	Society of Gynecologic Oncologists
SIGN	Scottish Intercollegiate Guidelines Network
SRL	Survey Research Lab
SSO	Society of Surgical Oncology
TEC	Blue Cross Blue Sheild Technology Evaluation Center
USPSTF	United States Preventive Services Task Force

Methodology

The Portland State University Survey Research Lab (SRL) was contracted by the Oregon Genetics Program (OGP) within the Office of Family Health in the Public Health Division at the Oregon Health Authority to conduct a survey of health insurers on their coverage of genetic testing, counseling, screening, and treatment for breast, ovarian, and colorectal cancer. The survey was undertaken as part of the Oregon Cancer Genomics Surveillance Program[1] being implemented by the OGP. A total of seven health insurance companies and six self-insurers were included in the study, which was conducted from February through June 2011. The research methodology and findings are presented in this report.

Research Objectives

This survey of health insurers was undertaken as part of the Oregon Cancer Genomics Surveillance Program, in order to evaluate health insurers' policies in Oregon for covering genetic tests, genetic counseling, as well as screening, procedures, and treatments aimed at decreasing the chance of developing cancer for individuals at increased risk for colorectal, breast, or ovarian cancer. The overarching questions guiding development of the survey instrument and implementation of the study are:

- What practice guidelines do the insurers use, and how do they use them in determining coverage?
- How do the insurers consider familial risk and genetic test results in coverage of screening and prophylactic procedures?
- Are there disparities in Oregonians' access to insurance coverage for genetic testing and genetic counseling for colorectal, breast, and ovarian cancer?
- Are insurers already complying with the Patient Protection and Affordable Care Act, Coverage of Preventive Health Services (PPACA)[2]?
- Are insurers considering changing their preventative services related to genetic risk for cancer to comply with PPACA, and if so, how?

The first goal of this study was to gather as much information as possible on the relevant coverage policies of the included insurance companies, in order to address the research questions and provide a body of data that could contribute to further investigation of the issue. As such, it was determined that a detailed analysis of disparities in Oregonians' access to coverage for the included services was beyond the scope of this study, although some preliminary information on variation in coverage across plans was collected. The remaining research questions were addressed through gathering available written policies and direct survey responses from health insurance providers and self-insuring companies.

[1] These efforts were supported by Cooperative Agreement #CDC-RFAGD08-801 (grant # 1U38GD000061) from the Centers for Disease Control and Prevention (CDC). The contents of this document are solely the responsibility of the authors and do not necessarily represent the official views of CDC.

[2] Full text of the Patient Protection and Affordable Care Act can be found at The Library of Congress online, at: http://thomas.loc.gov/cgi-bin/query/D?c111:7:./temp/~c111gjhu0j::

Sampling

The sample for this study included the seven largest health insurance companies in Oregon and six self-insurers. The difference between health insurance companies and self-insurers lies in who takes the risk for the actual cost of medical services. In this document, we define health insurance companies as companies that offer individual and/or group health insurance plans in which the individual or group (a group is usually an employer) pays a set amount to the company and the company pays or reimburses for the cost of health care services. Self-insured employers take on the risk for the actual cost of medical services themselves. Self-insured employers often contract with an insurance company to administer their plan. Health insurance companies can be self-insured. The list of seven health insurance companies was provided by OGP, while the list of self-insurers was compiled by the SRL. The names of the health insurance companies and self-insurers are not identified in this report.

The initial plan was to include self-insured organizations that covered around 250,000 lives in Oregon, or 50% of all lives covered by self-insurers in the state. Because there is no comprehensive list of self-insurers that covers only the state of Oregon, a list had to be compiled using multiple sources, including: www.freeerisa.com, the Portland Business Journal, the Oregon Business Journal, and the Oregon Public Employee Benefit Board. The Free Erisa website provides a database of self-insured businesses based on filings required by the Employee Retirement Income Security Act, a federal law requiring employers to file benefits information with the government. The limits of this website, however, are that it does not provide specific information on the number of employees in Oregon for companies in multiple states, and it does not provide information on self-insuring public agencies.

Additional information was gathered from lists published by the business journals of the largest employers in the state of Oregon[3]. These lists were used to identify which self-insuring companies had the most employees in the state. It should be noted that Health Insurance Company A (HIC-A) and HIC-B are among the largest self-insuring employers in Oregon, but were not considered because they were already included as health insurance companies. The six self-insuring companies included in the study were selected from among the largest employers in Oregon to provide a mix of sectors, industries and geographic location. **Table 1** presents the estimated number of lives covered under plans through the included self-insurers. Because detailed information on the number of lives covered in Oregon under plans offered by the four private sector self-insuring businesses was unavailable, an estimate was made based on the total number of employees in the state. **Table 2** presents the number of lives covered by each of the included health insurance companies[4].

[3] Oregon Business, July 2009 "Oregon's Top Private 150 Companies", Accessed at:
http://www.oregonbusiness.com/articles/62-july-2009/1908-oregons-top-private-150-companies
Portland Business Journal "Portland Metro's Largest Employers", Accessed at:
http://www.bizjournals.com/portland/blog/2011/05/list-portland-metros-largest-employers.html
[4] Health Insurance in Oregon 2011, Department of Consumer and Business Services
http://insurance.oregon.gov/health_report/3458-health_report-2011.pdf

Table 1: Lives Covered by Self-Insurers

Self-Insurers (SI)	Estimated Number of Lives Covered
SI-A (public sector)	170,000
SI-B (public sector)	126,293
SI-C (private sector)	15,000
SI-D (private sector)	12,000
SI-E (private sector)	8,233
SI-F (private sector)	7,500
Total	**339,026**

Table 2: Lives Covered by Health Insurance Companies

Health Insurance Company (HIC)	Number of Lives Covered in 2009
HIC-A	350,215
HIC-B	325,941
HIC-C	140,356
HIC-D	127,115
HIC-E	105,396
HIC-F	62,679
HIC-G	60,906
Total	**1,172,608**

Data Collection

Data was collected from insurers using a two-phased approach. In the first phase, online searches were conducted to find any available written policies related to genetic testing and counseling for the seven health insurance companies. In the second phase, health insurance companies and self-insurers were contacted directly to gather information. A survey instrument was developed and conducted either verbally over the phone, or in writing via email. The final survey script can be found in **Appendix A** of this report.

Written Policy Review

Prior to contacting organizations directly, online searches were conducted to find any relevant written policies for the seven health insurance companies. Searches were conducted within each of the seven company websites using the "site:" function with Google. This function allows a user to search a specific web address for the desired search terms, and is used by typing the target web address and search term into the Google search box using the following format: "Site:http://examplewebsite.com searchterm". The keywords used in the searches include:

Search Keywords

BRCA
Breast Cancer
Breast MRI
Chemoprevention
Colectomy
Colonoscopy
Colorectal Cancer
Gene
Genetic counseling
Genetic testing
HNPCC
Lynch Syndrome
Mammography
Mastectomy
MMR
Oophorectomy
Ovarian Cancer
Tamoxifen

Once relevant written policies were collected, they were reviewed for information to be added to a database that was constructed to allow for the storage and analysis of the questions as they are presented in the survey instrument. The written policies obtained during this study were provided in separate documents from this report.

Survey Implementation

Once available written policies had been collected online and reviewed, the health insurance companies and self-insurers were called directly and asked to complete the survey. The survey instrument was developed in consultation with OGP staff and included specific questions about coverage policies for

genetic testing and counseling related to breast, ovarian, and colorectal cancer; coverage policies for screening and prophylactic procedures for patients with positive genetic test results or who have been identified to be at increased familial risk; guidelines used to determine coverage policies; variations in coverage across plans or locations; and any changes anticipated in relation to PPACA.

The first point of contact with the health insurance companies were with customer service representatives, using phone numbers available on the respective company website. The customer service representative was asked if they could provide the needed information, or refer to a more appropriate contact. If an appropriate informant could not be reached through the customer service representative, then the next step was to contact a public or media relations representative – again using contact information found on the company website. Follow-up emails were also sent to the public relations representatives when possible. In a few cases, contact was made directly with personnel recommended by OGP. The title and responsibilities of the key informants at each company varied, and included management and administrative personnel as well as medical professionals.

Once contact had been established with a key informant, the project would be explained to them in more detail on the phone. Although the initial plan was to administer the survey over the phone, a number of informants requested a document with the questions be emailed to them. The final questionnaires completed by representatives at health insurance companies were done both by phone and email. For the private sector self-insuring organizations, contact information for the representative responsible for health benefits was obtained from the Free Erisa website. For the public sector self-insuring organizations, the public administrator in charge of the plans was contacted. In most cases, representatives from the self-insurance companies provided the name of the health care companies that administer their plans and determine the relevant coverage policies. Some self-insurers had multiple plans available to their Oregon employees, and in two cases these plans were administered by health insurance companies not included in the original list (HIC-H and HIC-I). In these cases, written policies were obtained where possible but direct contact with these health insurance companies was not made.

Response Rates

Some amount of data was obtained on all included organizations, with the exception of self-insurer D (SI-D). It was found that several of the health insurance companies also administered plans for some of the self-insurers. **Table 3** shows the health insurance companies that administer plans for the self-insured companies.

Table 3: Self-Insurers' Plan Administration

Self-Insurer	Plan Administrator	Plan Administrator	Plan Administrator
SI-A	HIC-B	HIC-A	HIC-E
SI-B	HIC-B	HIC-A	n/a
SI-D	Missing	n/a	n/a
SI-C	HIC-H	HIC-A	n/a
SI-E	Self-Administered	n/a	n/a
SI-F	HIC-I	HIC-A	n/a

It was confirmed through the written policies and speaking with the self-insurers that the HIC-A, HIC-B, and HIC-E-administered plans were goverened by the same policies set by those health insurance companies. SI-C and SI-F had plans available to their Oregon employees that were administered by HIC-H and HIC-I, respectively, and both referred us to the respective policies of those companies. In the case of HIC-H, however, it was not possible to confirm whether their colorectal cancer screening and prophylaxis coverage policies applied to the SI-C plan. The final list of health insurance companies and self-insurance

plans for which unique policy information was gathered, and will be reported on here, include:

Final Health Insurance Plans

HIC-A	HIC-C	HIC-E	HIC-G	HIC-I
HIC-B	HIC-D	HIC-F	HIC-H	SI-E

SI-A plans were administerd by HIC-A, HIC-B or HIC-E; SI-B plans were administered HIC-A or HIC-E; SI-C plans were administered by HIC-A or HIC-H; SI-D did not respond to multiple attempts to contact; SI-F plans were administered by HIC-A or HIC-I.

Written policies on genetic testing and counseling were obtained from all but HIC-A, HIC-F, SI-D, and SI-E. A HIC-A representative provided answers to the survey instrument, and explained that they did not have the kind of written policies that could be easily shared. A HIC-F representative also provided answers to the survey questions and stated that their policies were currently under revision and could not be released, while a SI-E representative indicated they did not have written policies for the included services. HIC-C and SI-D did not respond to requests for information during the data collection period, while HIC-G declined to participate in the survey. Written policies were obtained online or provided by respondents from the respective companies. **Table 4** details the plans for which written policies on cancer genetic testing were obtained, and organizations that respondend to the survey instrument.

Table 4: Policies and Survey Responses Collected

Organization	Obtained Written Policies on *BRCA* Testing	Obtained Written Policies on *MMR* Testing	Responded to Survey Questions
HIC-A	No	No	✓
HIC-B	✓	✓	✓
HIC-C	✓	✓	No Response
HIC-D	✓	✓	✓
HIC-E	✓	✓	✓
HIC-F	No	No	✓
HIC-G	✓	✓	Declined
HIC-H	✓	✓	Not Contacted[5]
HIC-I	✓	✓	Not Contacted
SI-D	No	No	No Response
SI-E	No	No	✓

[5] Some self-insurers had multiple plans available to their Oregon employees, and in two cases these plans were administered by health insurance companies not included in the original list. In these cases, written policies were obtained where possible but direct contact with these health insurance companies was not made.

Notes on Data and Analysis

Information on coverage policies and guidelines presented in this report was taken from both written policies and survey responses. In some cases, it was not possible to determine whether a service was covered or required because the respective written policy was not available, or the question was left blank by the survey respondent. In these cases, the information is reported as "missing" in the data tables. In other instances, the respective policy was available, but the information needed was not specified or could not be determined based on the content of the policy document. In these cases, the information is reported as "not specified" in the data tables. Because of the different types of data sources and variation used in policy language by the health insurance companies, it was necessary to develop criteria for determining if a service was covered. A service was determined to be "covered" if any of the following occured:

- A respondent provided a "yes" response to the respective question on the survey.
- The policy states the service is "covered."
- The policy states the service is considered "medically necessary" under the stated conditions.
- The service is described in a policy as a requirement for another service known to be covered.
- The policy guidelines state that the service should accompany another service known to be covered, without specifying its requirement.
- The policy indicates it is a covered service, but potentially subject to plan limitations.

Genetic Testing and Counseling

Information was obtained from the included companies on their coverage policies for breast cancer susceptibility gene 1 and 2 (*BRCA*) genetic testing in relation to breast and ovarian cancer, and mismatch repair gene (*MMR*) genetic testing in relation to colorectal cancer, as well as any required prior authorization procedures. Their coverage policies on related genetic counseling were also examined. With the exception of HIC-B and SI-E, all the included companies cover both *BRCA* and *MMR* testing for patients with or without cancer who met the relevant criteria. The majority also cover genetic counseling both with and without genetic testing, although complete informaiton on genetic counseling policies was not available for all companies. The following section presents the coverage policies for *BRCA1* and *BRCA2*, and *MMR* genetic testing, as well as coverage for related genetic counseling and prior authorization procedures.

BRCA and *MMR* Testing Coverage

Table 5 presents which companies cover *BRCA* and *MMR* genetic testing for patients who have no personal history of cancer, and for patients who either have or had a related cancer. All the included health insurance companies cover *BRCA* testing for patients both with and without a personal history of cancer, as well as *MMR* testing for patients with a personal history of cancer. SI-E indicated that it only covers genetic testing if the treating physician deems it medically necessary for diagnostic purposes, not for screening, while HIC-B's written policy indicates that it only covers *MMR* testing for patients who have or had cancer.

Table 5: Coverage of Cancer Genetic Tests

Organization	*BRCA* Testing for Patients without Cancer	*BRCA* Testing for Patients with Cancer	*MMR* Testing for Patients without Cancer	*MMR* Testing for Patients with Cancer
HIC-A	✓	✓	✓	✓
HIC-B	✓	✓	No	✓
HIC-C	✓	✓	✓	✓
HIC-D	✓	✓	✓	✓
HIC-E	✓	✓	✓	✓
HIC-F	✓	✓	✓	✓
HIC-G	✓	✓	✓	✓
HIC-H	✓	✓	✓	✓
HIC-I	✓	✓	✓	✓
SI-E	No	✓	No	✓

BRCA Testing Coverage Policies

Coverage policies for *BRCA* testing for all the health insurance companies require the patient to have a personal or family history of breast or ovarian cancer that indicates they are at increased risk of developing

heritable breast or ovarian cancer and are likely to carry a *BRCA* mutation, based on their specified criteria. In response to the survey question, the representative from HIC-A indicated the tests would be covered if the patient was "felt to be at notable risk". The following guidelines were specified by the listed companies:

Patient meets criteria for personal and family history indicating probability of mutation

HIC-A	HIC-D	HIC-G
HIC-B	HIC-E	HIC-H
HIC-C	HIC-F	HIC-I

The results will have a clinical utility for patient or other covered family members

HIC-A	HIC-C	HIC-G
HIC-B	HIC-E	SI-E

Testing should first be conducted on the affected family member when possible

HIC-A	HIC-G
HIC-D	HIC-I

In addition to the above, HIC-C's general genetic testing policy states "The test can be adequately interpreted" as a requirement to consider the test medically necessary. The available written policies also specify whether or not the BRACAnalysis Rearrangement Test (BART) is also covered. HIC-B's and HIC-I's written policies indicate that BART is considered investigational and not covered, while the policies of the five companies listed below indicate that they do cover BART in certain circumstances. BART is covered by these companies for patients considered to be at exceptionally high probability for carrying a mutation, or when patients are at exceptionally high probability for carrying a mutation and also test negative for sequence mutations and common large rearrangments included in the standard *BRCA* test.

Cover BRACAnalysis Rearrangment Test (BART)

HIC-C	HIC-E	HIC-I
HIC-D	HIC-G	

MMR Testing Coverage Policies

MMR genetic testing is conducted to determine the presence of a hereditary nonpolyposis colorectal cancer syndrome (HNPCC). The available written policies for health insurance companies refer to either or both HNPCC and Lynch Syndrome, without specifying a distinction between the two terms. The exception to this is the written policy for HIC-E, which states, "Hereditary nonpolyposis colorectal cancer syndrome is reserved for disorders that have similar phenotypes but none of the specific mutations involved in Lynch syndrome." The written policy for HIC-E specifies coverage of *MMR* testing only in relation to Lynch syndrome. The majority of the health insurance companies use the Amsterdam II and Revised Bethesda criteria for determining whether a patient qualifies for *MMR* testing based on personal and family history of related cancers. A few included modifications to the Amsterdam II criteria to account for small families. Other criteria specified by at least two of the health insurance companies include:

- Patient was diagnosed with endometrial cancer before age 50
- Patient has a first- or second-degree relative with a known HNPCC mutation.

HIC-B is the only health insurance company that does not cover *MMR* testing for patients without cancer. The written policy for HIC-B states that *MMR* testing is covered for patients who meet the listed criteria

and have or have had colorectal or endometrial cancer. The HIC-B policy further states that genetic testing of unaffected family members is considered screening and is not covered. The following guidelines were specified by the listed companies:

Patient meets Amsterdam II or Revised Bethesda Criteria

HIC-B	HIC-D	HIC-G
HIC-C	HIC-E	HIC-H

Patient meets other guidelines indicating probability of mutation

HIC-A	HIC-D	HIC-H
HIC-B	HIC-F	HIC-I
HIC-C	HIC-G	

The results will have a clinical utility for patient or other covered family members

HIC-A	HIC-C	HIC-G
HIC-B	HIC-E	SI-E

Testing should first be conducted on the affected family member when possible

HIC-A	HIC-G
HIC-D	HIC-I

The *MMR* genes associated with HNPCC or Lynch syndrome include MLH1, MSH2, MSH6, and PMS2. A number of the available written policies outlined which genes were included in the covered testing. Both HIC-B and HIC-G listed MLH1, MSH2, and MSH6 in their respective policies, but did not specify the exclusion of PMS2. HIC-B and HIC-C specified that MSH6 would be covered only after a negative result for MLH1 and MSH2. HIC-A, HIC-D, HIC-F, HIC-I did not specify which genes were included, while HIC-C and HIC-E policies listed all four genes.

Coverage of Genetic Counseling

Available written policies and survey responses were used to determine whether pre- and post-genetic test counseling was covered, and whether genetic counseling was covered for patients with an increased risk for breast, ovarian, or colorectal cancer without associated testing. In review of the written policies, the following criteria were used to determine whether counseling was a covered service:

- The policy states the service is "covered."
- The policy guidelines state that the service should accompany another service known to be covered, without specifying its requirement.
- The policy indicates it is a covered service, but potentially subject to plan limitations.
- Documentation of counseling was outlined as a criteria for testing to be considered medically necessary.
- Documentation of counseling or a counseling plan was outlined as a condition necessary for pre-approval of genetic testing.

The final two criteria above, the documentation of counseling being necessary for prior authorization or coverage of genetic testing, were used to determine whether counseling was required for genetic testing.

Table 6 and **Table 7** outline the coverage of genetic counseling related to hereditary breast and ovarian cancer, and colorectal cancer, respectively.

Table 6: Coverage of Genetic Counseling for Breast and Ovarian Cancer

Organization	Counseling with *BRCA* Testing	Counseling for High-Risk Patients without *BRCA* Testing	Counseling required with *BRCA* Testing
HIC-A	✓	✓	✓
HIC-B	✓	✓	✓
HIC-C	✓	✓	✓
HIC-D	✓	✓	✓
HIC-E	✓	✓	✓
HIC-F	✓	✓	✓
HIC-G	✓	Missing	Not Specified
HIC-H	✓	No	Not Specified
HIC-I	✓	Missing	✓
SI-E	No	No	Not Applicable

Only SI-E indicated they do not cover genetic counseling, while HIC-I's written policies indicated genetic counseling was covered if a patient was recommended for genetic testing that was also covered under their plan. The policy also noted that many HIC-I plans limit coverage to three visits for both pre- and post-test counseling per year, although it was not possible to determine whether this particular limitation applied to the SI-C HIC-I plan. The HIC-I written policies further stated that individuals undergoing genetic testing should receive both pre- and post-test genetic counseling, but did not specify the requirement for coverage of genetic testing. Similarly, the written policy on *BRCA* testing from HIC-G stated that patients should receive pre- and post-test genetic counseling, but did not specify its requirement. In contrast, the HIC-G policy on *MMR* testing stated that documentation of pre-test genetic counseling is a needed to consider *MMR* testing medically necessary. The written policy on *BRCA* testing for HIC-B states that documentation of genetic counseling is required for pre-approval of testing, but the corresponding policy for *MMR* testing contains no language related to genetic counseling, and the HIC-B representative noted that no genetic counseling is covered with MMR testing.

The representative from HIC-A noted that patients are referred to an internal genetics center for evaluation for genetic testing, a process which includes genetic counseling, with post-test counseling available and covered for patients who receive testing. They reported that in relation to *MMR* testing, counseling is only required if the test is conducted on a blood sample; if testing is conducted on a colon tumor due to MSI histology, or because the patient was under 60 years old at diagnosis, counseling is not required. They further noted that cancer genetic counseling is a covered benefit for all policyholders, and does not require a physician's referral. Patients who test positive for *BRCA* or *MMR* mutations are seen for a one-year follow-up, if they desire. The HIC-F representative also reported they cover counseling for patients without accompanying testing, noting that they have no specific limitation or access requirement for genetic counseling. The HIC-F representative also reported that some level of counseling was required for *BRCA* testing, but not *MMR* testing.

Table 7: Coverage of Genetic Counseling for Colorectal Cancer			
Organization	Counseling with *MMR* Testing	Counseling for High-Risk Patients without *MMR* Testing	Counseling required with *MMR* Testing
HIC-A	✓	✓	Varies
HIC-B	No	No	Not Applicable
HIC-C	✓	✓	Not Specified
HIC-D	✓	✓	Not Specified
HIC-E	✓	✓	✓
HIC-F	✓	✓	No
HIC-G	✓	Missing	✓
HIC-H	✓	No	Not Specified
HIC-I	✓	Missing	✓
SI-E	No	No	Not Applicable

The representative from HIC-D and corresponding written policies indicated that counseling was part of the process of evaluating patients prior to *BRCA* testing. The written policy also indicated that counseling required to consider testing medically necessary. The written policy on *MMR* testing states that pre- and post-test counseling may be considered medically necessary along with testing, but does not specify whether counseling is required. The HIC-D respondent also indicated that genetic counseling would most likely be covered for high-risk patients independent of testing, depending on the respective plan language. The representative from HIC-E similarly reported that genetic counseling was covered independent of genetic testing for “appropriate eligible members.”

HIC-C and HIC-H were the only companies for which separate written policies on genetic counseling were obtained. The policy for HIC-C indicated that genetic counseling is considered medically necessary for patients who have a personal or family history of an inherited cancer. The written policy on *BRCA* testing for HIC-C stated that if prior authorization is required by the plan, it must include a documented “plan for pre- and post-test counseling.” The written policies on *BRCA* and *MMR* testing for HIC-I state that testing is appropriate only when trained professionals can provide pre- and post-test counseling. Both policies also state that testing may be considered medically necessary only when the criteria are met and testing is associated with genetic counseling.

Professionals Covered for Genetic Counseling

Table 8 presents the types of professionals that are covered by the respective companies for conducting genetic counseling. Information for HIC-A, HIC-B, HIC-D, HIC-E, and HIC-F was taken from survey responses, while informaiton for HIC-G, HIC-H, and HIC-I was taken from the language used in the respective genetic counseling or genetic testing policies. HIC-B and HIC-C policies did not specify which kinds of professionals would or would not be covered for genetic counseling. The written policy for HIC-D indicated that there was no specific CPT code for genetic counseling associated with testing, and that codes for an office visit may be used. It further stated that such counseling would typically be performed by a medical oncologist, medical geneticist, or psychotherapist. The HIC-F representative clarified in their survey response that attending physicians may provide the genetic counseling if they are adequately trained and documentation of the counseling is provided in the chart notes.

Table 8: Professionals Covered for Genetic Counseling

Organization	Types of Professionals Covered
HIC-A	"Genetic Counselors and Geneticists"
HIC-B	"Qualified provider – certified genetic counselor or a liscensed physician"
HIC-C	Not Specified
HIC-D	"Professionals meeting contract licensing"
HIC-E	"Professionals licensed by the appropriate authority"
HIC-F	"Geneticists, Certified Genetic Counselors, and adequately trained attending physicians"
HIC-G	Qualified professional
HIC-H	Physician or licensed, certified Genetic Counselor
HIC-I	Adequately trained health care professionals
SI-E	Not Applicable

Prior Authorization for Genetic Testing

The survey responses or written policies for HIC-E, HIC-F, and HIC-B clearly indicated that prior authorizaiton was required for both *BRCA* and *MMR* testing. The HIC-A representative reported that prior authorization was not required, but patients do have to see the HIC-A internal genetics center for counseling and evaluation prior to testing. They noted that the patient's personal medical history and family history are carefully reviewed, and the impact that a positive result would have on their or other family member's care is carefully considered when deciding who is offered testing. The HIC-D representative indicated in their survey response that formal prior authorization may be required for some procedures, but did not specify whether it was required in the case of either *BRCA* or *MMR* testing. They noted that the medical policy and contract language was used to determine coverage in the event of prior authorization, and that approval could be given by a registered nurse.

The HIC-E representative reported that physicians must submit clinical information for prior authorization, with the final decision being made by the medical director who uses medical necessity guidelines developed in-house for *BRCA* testing and Milliman guidelines for *MMR* testing. The written policy clarifies that physician chart notes and a family history must be submitted with the prior authorization request. The HIC-F representative reported that the physician submits requests for prior authorization, and the determination will be made by a nurse if the case clearly meets the applicable criteria, or it will be made by the medical director if it does not.

The written policy for *BRCA* testing for HIC-C indicates that the requirement for prior authorization varies among regional plans, and information related to their plans in Oregon was not available. It noted that if documentation for prior authorization was required, the physician must submit a full history and a plan for pre- and post-genetic test counseling. There was no reference to prior authorization in the written policies for *MMR* testing for HIC-C. The written *BRCA* testing policy for HIC-B stated that documentation of genetic counseling and medical and family history meeting National Comprehensive Cancer Network (NCCN) was required. While the written policy for *MMR* testing for HIC-B states that authorization is required, the exact process is not specified. Although the SI-E representative reported that prior authorization is required for diagnostic genetic tests, information on the prior authorization process was unavailable.

Table 9: Require Prior Authorization for Genetic Testing

Organization	Prior Authorization for *BRCA* Test	Prior Authorization for *MMR* Test
HIC-A	No	No
HIC-B	✓	✓
HIC-C	Not Specified	Not Specified
HIC-D	Not Specified	Not Specified
HIC-E	✓	✓
HIC-F	✓	✓
HIC-G	Not Specified	Not Specified
HIC-H	Not Specified	Not Specified
HIC-I	Not Specified	Not Specified
SI-E	✓	✓

Cancer Screening and Prophylaxis

Written policies and survey responses were reviewed to determine coverage of screening at younger ages or more frequent intervals, and coverage of prophylactic procedures for patients at increased risk of cancer. Where written policies or responses were available, coverage for such procedures was generally the same for high-risk patients whether or not they had tested positive for *BRCA* or *MMR* mutation.

Breast and Ovarian Cancer Screening and Prophylaxis

In considering coverage of increased breast and ovarian cancer screening for high-risk patients, the following procedures and guidelines were included:

- Mammography, Breast MRI, and other screening technologies at younger ages and/or shorter intervals than recommended for women at average risk for breast cancer
- Bilateral mastectomy
- Relevant ovarian cancer screening, such as CA-125 and trans-vaginal ultrasound
- Hysterectomy and bilateral salpingo-oophorectomy
- Chemoprophylaxis

Because written policies were not consistently available for all the included screening procedures for each company, coverage was deteremined based on those policies that were available. For example, although a policies on coverage guidelines for mammograms may have been unavailable, a policy on Breast MRIs may indicate that such screening technology is covered for women at increased risk due to family history or a positive *BRCA* test. In this case, the respective health insurance company would be recorded as covering increased screening. No written policies were available on the relevant procedures from HIC-G. Survey responses, but no written policies on the respective procedures, were available for HIC-A, HIC-B, HIC-E, and HIC-F. Some written policies and survey responses were available for HIC-D. The SI-E representative reported that genetic test results or family history have no effect on coverage of other procedures. Written policies were available for the following procedures for the respective insurance companies:

HIC-C

Breast MRI
Prophylactic Mastectomy
Prophylactic Bilateral Oophorectomy

HIC-D

Breast MRI
Prophylactic Mastectomy

HIC-H

Mammography
Breast MRI
Prophylactic Mastectomy
Trans-Vaginal Ultrasound
Prophylactic Oophorectomy

HIC-I

Breast MRI

Table 10 presents coverage of screening and prophylactic procedures for patients who have tested positive for *BRCA*1 or *BRCA*2 (*BRCA*+).

Table 10: Coverage of Screening and Prophylaxis for *BRCA*+ Patients

Organization	Increased Breast Cancer Screening	Bilateral Mastectomy	Ovarian Cancer Screening	Hysterectomy and Bilateral Salpingo-oophorectomy	Chemo-prophylaxis
HIC-A	✓	✓	✓	✓	✓
HIC-B	✓	✓	✓	✓	✓
HIC-C	✓	✓	Missing	✓	Missing
HIC-D	✓	✓	✓	✓	✓
HIC-E	✓	✓	✓	✓	✓
HIC-F	✓	✓	✓	✓	✓
HIC-G	Missing	Missing	Missing	Missing	Missing
HIC-H	✓	✓	✓	✓	Missing
HIC-I	✓	Missing	Missing	Missing	Missing
SI-E	No	No	No	No	No

The HIC-D representative noted in their comments that chemoprophylaxis would be covered if it is considered a 1 or 2A recommendation by the National Comprehensive Cancer Network (NCCN). The NCCN guidelines indicate that Tamoxifen is a 2A recommendation for breast cancer risk reduction for women age 35 or over who meet the criteria for increased familial risk, including those who are *BRCA* positive. Although no written policies related to chemoprophylaxis were available for a number of the health insurance companies, it should be noted that the United States Preventive Services Task Force (USPSTF) makes the following Grade B recommendation related to chemoprophylaxis: "The USPSTF recommends that clinicians discuss chemoprevention with women at high risk for breast cancer and low risk for adverse effects of chemoprevention. Clinicians should inform patients of the potential benefits and harms of chemoprevention." In addition to the written policy on mammograms from HIC-H, their website indicates that the screening is covered at the frequency recommended by the patient's physician.

Table 11 presents coverage of the same screening and prophylactic procedures for patients who have a family history indicated increased risk of breast or ovarian cancer, but do not have have a positive *BRCA* test result. While the survey instrument specified, "Patients with increased familial risk of breast or ovarian cancer, but had no *BRCA* test, a result of *BRCA* negative, or a result of variants of uncertain significance," the written policies specified only increased familial risk as criteria, and did not include any limitations or guidelines related to a result of *BRCA* negative or variants of uncertain significance. Representatives from HIC-A and HIC-F both reported that coverage of increased screening or prophylactic procedures in the case of high-risk pateints without a *BRCA* positive test would vary. The HIC-A representative noted that coverage would depend on the patient's history, while the HIC-F representative clarified that coverage would depend on the level of risk, recommendations by the genetic counselor or attending physician, and guidelines by the NCCN or other authoritative groups.

Table 11: Coverage of Screening and Prophylaxis for High-Risk Patients without *BRCA*+ Test

Organization	Increased Breast Cancer Screening	Bilateral Mastectomy	Ovarian Cancer Screening	Hysterectomy and Bilateral Salpingo-oophorectomy	Chemo-prophylaxis
HIC-A	Varies	Varies	Varies	Varies	Varies
HIC-B	✓	✓	✓	✓	Missing
HIC-C	✓	✓	Missing	✓	Missing
HIC-D	✓	✓	Missing	Missing	✓
HIC-E	✓	✓	✓	✓	✓
HIC-F	Varies	Varies	Varies	Varies	Varies
HIC-G	Missing	Missing	Missing	Missing	Missing
HIC-H	✓	✓	✓	✓	Missing
HIC-I	✓	Missing	Missing	Missing	Missing
SI-E	No	No	No	No	No

Colorectal Cancer Screening and Prophylaxis

In considering coverage of increased breast and ovarian cancer screening for high-risk patients, the following procedures and guidelines were included:

- Colonoscopy, Fecal Occult Blood Test (FOBT), sygmoidoscopy, or other screening procedures at younger ages and/or shorter intervals than recommended for people at average risk for colorectal cancer
- Colectomy or other relevant intestinal surgeries
- Chemoprophylaxis

As with the breast and ovarian cancer screening policies, coverage for increased colorectal cancer screening was determined using those written policies that were available. **Table 12** presents coverage of colorectal cancer screening and prophylaxis for patients who have a *MMR* positive (*MMR*+) test result. No written policies were available for HIC-A, HIC-B, HIC-D, HIC-E, HIC-F, HIC-G, or HIC-I. Survey responses were available for HIC-A, HIC-B, HIC-D, HIC-E, and HIC-F. The HIC-D representative noted that a colectomy would be covered without review, while coverage of chemoprophylaxis would again depend on the NCCN guideline. No information on the NCCN guideline related to chemoprophylaxis for reducing risk of colorectal cancer was available. The HIC-F representative reported that they currently have no policies related to colectomy or chemoprophylaxis. For HIC-C, only a written policy on coverage of colonoscopies was available. A general colorectal cancer screening policy was available for HIC-H. This policy indicated that colorectal cancer screening in general may not be covered by all HIC-H plans, but noted that in cases where coverage is available, it includes more intensive screening for high-risk and *MMR* positive patients. Covered procedures for high-risk and *MMR* positive patients includes FOBT, fecal DNA, flexible sygmoidoscopy, double-contrast barium enema, colonoscopy, and computed tomographic cologracy. Although it was not possible to confirm directly whether colorectal cancer screening is covered for the SI-C HIC-H plan, it is presumed that benefit matching for the alternative SI-C HIC-A plan makes it likely that such services are covered.

Table 12: Coverage of Screening and Prophylaxis for *MMR*+ Patients

Organization	Increased Colorectal Cancer Screening	Colectomy or other relevant surgeries	Chemoprophylaxis
HIC-A	✓	✓	✓
HIC-B	✓	Missing	Missing
HIC-C	✓	Missing	Missing
HIC-D	✓	✓	Missing
HIC-E	✓	✓	✓
HIC-F	✓	No policy	No Policy
HIC-G	Missing	Missing	Missing
HIC-H	✓	Missing	Missing
HIC-I	Missing	Missing	Missing
SI-E	No	No	No

Table 13 presents coverage of increased screening and prophylactic procedures for patients at increased risk of colorectal cancer, but without an *MMR* positive test. The survey instrument specified, "Patients with increased familial risk of colorectal cancer, but had no *MMR* test, *MMR* negative results, or variants of uncertain significance," although the written policies that were available did not specify any limitations or guidelines related to a test result of *MMR* negative or variants of uncertain significance. The HIC-A representative again noted that coverage of screening and prophylactic procedures in these cases would depend on the patient's history. The HIC-F representative reported that they currently had no policy related to chemoprophylaxis.

Table 13: Coverage of Screening and Prophylaxis for High-Risk Patients without *MMR*+ Test

Organization	Increased Colorectal Cancer Screening	Colectomy or other relevant surgeries	Chemoprophylaxis
HIC-A	Varies	Varies	Varies
HIC-B	Missing	Missing	Missing
HIC-C	✓	Missing	Missing
HIC-D	✓	✓	Missing
HIC-E	✓	✓	✓
HIC-F	✓	✓	No Policy
HIC-G	Missing	Missing	Missing
HIC-H	✓	Missing	Missing
HIC-I	Missing	Missing	Missing
SI-E	No	No	No

Practice Guidelines

To better understand how and which guidelines were used in the formation of coverage policies, written policies and survey responses were reviewed to evaluate how external guidelines were referenced. The following section presents which policies are based on guidelines, and what guidelines were reported. The following criteria were used to determine if a given policy was based on specific guidelines:

- A survey respondent provided an affirmative answer and outlined the practice guidelines used by their company.
- A written policy clearly identifies coverage criteria as being established by a professional society.
- A written policy clearly identifies guidelines as forming the basis of their coverage policy.

If those criteria were not met, but professional societies and guidelines were otherwise referenced in a written policy, the respective policy is listed as "not specified" in the data tables below. However, the professional societies and guidelines referenced are still included in subsequent tables. A number of written policies included substantial literature reviews and background information, with journal articles and practice guidelines cited in the references. Only the professional societies are listed in the following section, except where a policy was clearly stated to be based on other published research.

Breast and Ovarian Cancer Policy Guidelines

Table 14 lists the coverage policies, related to genetic testing, screening, and prophylaxis for patients at increased risk of breast and ovarian cancer, that are based on practice guidelines. Survey respondents for HIC-A, HIC-B, HIC-D, HIC-E, and HIC-F all reported their coverage policies related to breast and ovarian cancer were based on guidelines. The written policies available for the remaining companies all referenced some kind of guidelines in the document, although not all of them specified that those guidelines formed the basis of the respective policy.

Table 14: Breast and Ovarian Cancer Policies Based on Practice Guidelines

Organization	*BRCA* Testing and Counseling	Breast and Ovarian Cancer Screening	Breast and Ovarian Cancer Prophylaxis
HIC-A	✓	✓	✓
HIC-B	✓	✓	✓
HIC-C	✓	✓	✓
HIC-D	✓	✓	✓
HIC-E	✓	✓	✓
HIC-F	✓	✓	✓
HIC-G	Not Specified	Missing	Missing
HIC-H	Not Specified	Not Specified	Not Specified
HIC-I	Not Specified	Not Specified	Missing
SI-E	Missing	Not applicable	Not Applicable

Table 15 outlines the practice guidelines and professional societies that were referenced by the written policies and survey respondents in relation to breast and ovarian cancer. Using both the survey responses and available written policies, information in this section relates to the following procedures for the respective companies:

HIC-A
BRCA Testing and Counseling
Breast MRI
Unspecified prophylactic procedures

HIC-B
BRCA Testing and Counseling
Unspecified screening procedures
Unspecified prophylactic procedures

HIC-C
BRCA Testing and Counseling
Breast MRI
Prophylactic Mastectomy
Prophylactic Oophorectomy

HIC-D
BRCA Testing and Counseling
Breast MRI
Prophylactic Mastectomy

HIC-E
BRCA Testing and Counseling
Unspecified screening procedures
Unspecified prophylactic procedures

HIC-F
BRCA Testing and Counseling
Unspecified screening procedures
Unspecified prophylactic procedures

HIC-G
BRCA Testing and Counseling

HIC-H
BRCA Testing and Counseling
Mammography
Breast MRI
Trans-Vaginal Ultrasound
Prophylactic Mastectomy
Prophylactic Oophorectomy

HIC-I
BRCA Testing and Counseling
Breast MRI

The HIC-A representative reported they used the American Cancer Society (ACS) guidelines for screening MRIs, but were unable to report the guidelines used by the overall HIC-A system in relation to breast and ovarian cancer (BOC) screening for high-risk patients. They also noted that clinical judgment was used along with the guidelines for determining coverage of *BRCA* testing and related prophylactic procedures. It should be noted that the policies listed in **Table 15** represent the most complete information available, but may not represent an exhaustive list of guidelines actually used in the formation of coverage policies.

Table 15: Practice Guidelines for Breast and Ovarian Cancer Coverage Policies

Organization	Guidelines Used in *BRCA* Testing and Counseling Policies	Guidelines Used in BOC Screening Policies	Guidelines Used in BOC Prophylaxis Policies
HIC-A	NCCN	ACS	NCCN
HIC-B	NCCN, USPSTF	NCCN	NCCN
HIC-C	ACOG, ACMG, ASBS, ASCO, ASHG, NACHGR, NBCC, NCCN, NCI, NSGC, USPSTF, Brigham and Women's Hospital[6]	ACR, ACS, AHRQ, ASBS, ISCI, TEC Assessments	ACOG, ACMG, ACS, ASBS, NCCN, NCI, NGC, USPSTF
HIC-D	1997 TEC Assessment, ACMG, ASCO, NCCN, USPSTF	TEC Assessments, ACR, ACS	1999 TEC Assessment, Hartmann 1999[7]
HIC-E	Milliman, NCCN	Milliman	Milliman
HIC-F	ACS, Milliman, NCCN	ACS, Milliman, NCCN	ACS, Milliman, NCCN
HIC-G	1997 TEC Assessment, ASCO, ACMG, NCCN, USPSTF	-	-
HIC-H	ACMG, ACOG, ACSO, NCCN, USPSTF	ACOG, ACR, ACS, ASBS, NCCN, NCI, SBI/ACR, USPSTF	ACOG, ASPS, NCCN, NCI, NHCTF, NICE, SIGN, SSO, USPSTF
HIC-I	ACMGF, ACOG, NCCN	ACS, ACR, ASBS, ASCO, NCCN, USPSTF	-
SI-E	-	-	-

Colorectal Cancer Policy Guidelines

Table 16 lists the coverage policies, related to genetic testing, screening, and prophylaxis for patients at increased risk of colorectal cancer, that are based on practice guidelines. In contrast to the *BRCA* policies, all but HIC-I's written policies on *MMR* testing specified established practice guidelines as the basis of coverage policies.

[6] Brigham and Women's Hospital. Breast disease. Guide to prevention, diagnosis and treatment. Boston, MA: Brigham and Women's Hospital; 2001. Available at: http://www.guideline.gov/summary/summary.aspx?ss=6&nbr=002657&doc_id=3431

[7] Hartmann LC, Schaid DJ, Woods JE, et al. Efficacy of bilateral prophylactic mastectomy in women with a family history of breast cancer. N Eng J Med 1999; 340(2):77-84.

Table 16: Colorectal Cancer Policies Based on Practice Guidelines

Organization	*MMR* Testing and Counseling	Colorectal Cancer Screening	Colorectal Cancer Prophylaxis
HIC-A	✓	Missing	Missing
HIC-B	✓	✓	Missing
HIC-C	✓	✓	Missing
HIC-D	✓	Missing	✓
HIC-E	✓	✓	✓
HIC-F	✓	✓	✓
HIC-G	✓	Missing	Missing
HIC-H	✓	✓	Missing
HIC-I	Not Specified	Missing	Missing
SI-E	Missing	Not Applicable	Not Applicable

Table 17 outlines the practice guidelines and professional societies that were referenced by the written policies and survey respondents in relation to hereditary colorectal cancer. Using both the survey responses and available written policies, information in this section relates to the following procedures for the respective companies:

HIC-A
MMR Testing and Counseling

HIC-B
MMR Testing and Counseling
Unspecified screening procedures

HIC-C
MMR Testing and Counseling
Colonoscopy

HIC-D
MMR Testing and Counseling
Chemoprophylaxis

HIC-E
MMR Testing and Counseling
Unspecified screening procedures
Unspecified prophylactic procedures

HIC-F
MMR Testing and Counseling
Unspecified screening procedures
Unspecified prophylactic procedures

HIC-G
MMR Testing and Counseling

HIC-H
MMR Testing and Counseling
Colonoscopy
FOBT
Sygmoidoscopy

HIC-I
MMR Testing and Counseling

The HIC-A representative reported they did not know what guidelines the HIC-A system or HIC-A surgeons used for determining coverage of screening and prophylactic procedures for high-risk patients. The policies listed in Table 17 represent the most complete information available, but may not represent an exhaustive list of guidelines actually used in the formation of coverage policies.

Table 17: Practice Guidelines for Colorectal Cancer Coverage Policies

Organization	Guidelines Used *MMR* Testing and Counseling Policies	Guidelines Used in Colorectal Cancer Screening Policies	Guidelines Used in Colorectal Cancer Prophylaxis Policies
HIC-A	NCCN	-	-
HIC-B	Amsterdam II and Revised Bethesda, Noridian Medicare LCD	Noridian Medicare LCD	Noridian Medicare LCD
HIC-C	ACOG, AGA, Amsterdam II and Revised Bethesda, ASCRS, EGAPP, NCCN, NCI, NSGC	ACG, ACR, ACS, AGA, ASCRS, ASGE, NCCN, USPSTF	-
HIC-D	Amsterdam II and Revised Bethesda, TEC Assessments	-	NCCN
HIC-E	Amsterdam II and Revised Bethesda, Milliman	Milliman	Milliman
HIC-F	ACS, NCCN, Milliman	ACS, NCCN, Milliman	ACS, NCCN, Milliman
HIC-G	AHRQ, Amsterdam II and Revised Bethesda, EGAPP	-	-
HIC-H	ACMG, AGA, Amsterdam II and Revised Bethesda, ASCO, ASCRS, ASHG, NCCN, SGO	ACS, NCCN	-
HIC-I	AGA, ASCO, NCCN	-	-
SI-E	-	-	-

Variations in Coverage

Survey respondents were asked if there were any variations in coverage across the plans they offered in relation to the included services, or if there were any additional costs or subsidies for patients in rural areas. In addition to the survey responses, HIC-H's written policy on colorectal cancer screening indicated that such screening services are not necessarily covered by all plans; however, it is not expected that this affects the SI-C self-insurance plan of interest in this report. Only the HIC-E representative reported that there were any differences in cost coverage for rural patients. They reported that travel expenses were generally not covered, but out of network providers were subsidized, albeit at a reduced rate. They noted additionally, that "licensed practitioners are reimbursed based on the medically necessary procedures they are qualified to perform." None of the survey respondents indicated there were fundamental differences in coverage among their commercial insurance plans. HIC-E reported that some employers offering self-insurance plans administered by HIC-E include additional screening and prevention benefits for their covered employees. The HIC-A representative indicated only that the co-pays and co-insurance paid by patients may vary depending on the type of coverage they have. The HIC-F representative reported that, "Medicare, medicaid, self-insured, and commercial plans have some differences depending on the standards set by the agencies or contract."

Compliance with PPACA

The Patient Protection and Affordable Care Act (HR 3590; PPACA) was passed on March 23, 2010, and includes requirements for coverage of preventative services within six months of enactment. Per Section 2713, Coverage of Preventive Health Services, "a group health plan and a health insurance issuer offering group or individual health insurance coverage shall provide coverage for and shall not impose any cost sharing requirements for evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the US Preventive Services Task Force (USPSTF)". The USPSTF currently recommends referral for *BRCA* counseling and evaluation for testing for patients with a family history that puts them at increased likelihood of having a *BRCA1* or *BRCA2* mutation, and rates this as a "B" recommendation.

Of the plans included in this report, commercial plans operated by the following health insurance companies are subject to PPACA requirements: HIC-A, HIC-B, HIC-C, HIC-D, HIC-E, HIC-F, and HIC-G. The specific plans operated by HIC-H and HIC-I that are of interest to this report, as well as SI-E, are self-insurance plans that would be granted "grandfathered" status and exempt from the preventive services coverage requirements. Details regarding whether the HIC-H plan for SI-C or the HIC-I plan for SI-F were already meeting the PPACA requirements, however, were unavailable. In determining compliance by the relevant health insurance companies, their written policies on *BRCA* testing and counseling, any survey responses, and official statements regarding implementation of PPACA were reviewed. The following criteria were used:

- Do they cover *BRCA* testing for patients at increased likelihood of having *BRCA1* or *BRCA2* mutations based on family history?
- Do they cover genetic counseling related to *BRCA* testing?
- Have they eliminated cost-sharing on *BRCA* testing and counseling?

Table 18 illustrates compliance of the seven health insurance companies with these PPACA requirements.

Table 18: Compliance with PPACA for *BRCA* Counseling and Testing

Organization	Cover *BRCA* Testing and Counseling per USPSTF Guidelines	Eliminated Cost Sharing on Applicable Plans	Complying with PPACA
HIC-A	✓	✓	★
HIC-B	✓	✓	★
HIC-C	✓	✓	★
HIC-D	✓	✓	★
HIC-E	✓	✓	★
HIC-F	✓	✓	★
HIC-G	✓	✓	★

Plans that an individual was enrolled in prior to March 23, 2010 and that do not make substantive changes to any coverage policies are considered "grandfathered" and exempt from the preventive services coverage requirement. This includes any self-insurance or self-administered plans, but would also include some existing commercial plans operated by health insurance companies. Statements and benefit updates from the health insurance companies were reviewed for indications of how they would be implementing the preventive services coverage requirements in relation to any grandfathered plans. Both HIC-A and HIC-B published statements outlining how preventive services would be covered in full as plans renewed. Neither statement referenced grandfathered plans, and the language used implied that preventive services coverage would generally apply to all plans administered by them. HIC-F also released a statement outlining their compliance with PPACA, and stated that all small group and individual plans would be adjusted to comply with the preventive services coverage requirements, while "fully insured large groups will be automatically moved to a nongrandfathered plan" unless the group decides otherwise. HIC-G also indicated that they will transition any individual or small group plans that are currently being marketed, but will maintain grandfathered status for plans that have been closed to new enrollment or scheduled for discontinuation until they are no longer available.

No clear information was available related to how HIC-E would be managing grandfathered plans, while language used in the informational document from HIC-C indicated they would be maintaining grandfathered plans. HIC-D clearly indicated they would be maintaining grandfathered plans for their customers, who would have the option of switching to a non-grandfathered plan. Additionally, they noted that individual and group members who switched to a non-grandfathered plan between March 23 and June 14, 2010, would have the option of switching back to their original grandfathered plan. Preventive services coverage will be required of grandfathered plans in 2014.

Changes for PPACA

Survey respondents were also asked if they anticipated any changes being made to their current policies related to genetic risk for cancer in order to comply with PPACA. The representatives from HIC-A and HIC-D responded that they did not anticipate any changes. The representative from HIC-E reported that their "preventive care services reimbursement will be in full compliance with federal and state legislation." The representative from HIC-F indicated they were anticipating changes, but noted that, "Some changes are already in place with respect to 'preventive screening', e.g., colonoscopy screening now first dollar coverage." The representative from SI-E noted that they did anticipate changes, stating that their policies are reviewed annually to ensure compliance with applicable laws and regulations.

Appendix A: Survey Instrument

Cancer Genetic Insurance Questions for Insurers

Q1a. Do you have written policies on your coverage of cancer genetic testing, counseling, and follow-up procedures for breast and ovarian cancer? [If yes, can we get a copy?]

- Yes, can get a copy of written policies
- Have written policies, but won't release copies
- No, no written policies

Q1b. Do you have written policies on your coverage of cancer genetic testing, counseling, and follow-up procedures for colorectal cancer? [If yes, can we get a copy?]

- Yes, can get a copy of written policies
- Have written policies, but won't release copies
- No, no written policies

IF Q1a and Q1b = YES → Q16 [Other Questions]
IF Q1a = NO or Won't Release → Q2 [Breast and Ovarian Cancer Coverage Policies]
IF Q1b = NO or Won't Release → Q9 [Colorectal Cancer Coverage Policies]

Breast and Ovarian Cancer Coverage Policies

Q2. Do you ever cover BRCA testing for people without cancer?

- Yes [What is your coverage policy?] ____________________
- No [Why not?] ____________________

Q3. Do you ever cover BRCA testing for people with cancer?

- Yes [What is your coverage policy]? ____________________
- No [Why not?] ____________________

IF Q2 or Q3 = "PRIOR AUTHORIZATION" → Q4
IF Q2 and Q3 = YES and ≠ "PRIOR AUTHORIZATION" → Q5
IF Q2 and Q3 = NO →Q6

Q4. What is the process for prior authorization? ____________________

a) What does the patient have to do to apply for prior authorization?
b) Who makes the final determination?
c) What standards or guidelines, if any, are used in making prior authorization decisions?

Q5. Do you ever cover pre- or post- genetic counseling for BRCA testing?

- Yes [What is your coverage policy?] ______________________________
- No [IF NO →Q6]

Q5a. Is pre- and post-genetic counseling a requirement for getting BRCA testing?

- Yes
- No

Q6. Do you ever cover genetic counseling for patients with increased familial risk of breast or ovarian cancer, without BRCA testing?

- Yes [What is your coverage policy?] ______________________________
- No

IF Q5 or Q6 = YES →Q7
IF Q5 and Q6 = NO → Q8

Q7. Which types of professionals are covered for genetic counseling related to BRCA and breast and ovarian cancer? ______________________________

Q8. What screening and prophylactic procedures are covered for…

A. BRCA Positive patients?

- ☐ Mammography, Breast MRI, other screening technologies at younger ages and/or shorter intervals than recommended for women at average risk for breast cancer ______________
- ☐ Bilateral mastectomy ______________________________
- ☐ Relevant ovarian cancer screening, such as CA-125 and vaginal ultrasound______________
- ☐ Hysterectomy and bilateral salpingo-oophorectomy ______________________
- ☐ Chemoprophylaxis ______________________________
- ☐ Other: ______________________________

B. Patients with increased familial risk of breast or ovarian cancer, but had no BRCA test, a result of BRCA Negative, or a result of variants of uncertain significance?

- ☐ Mammography, Breast MRI, other screening technologies at younger ages and/or shorter intervals than recommended for women at average risk for breast cancer ______________
- ☐ Bilateral mastectomy ______________________________
- ☐ Relevant ovarian cancer screening, such as CA-125 and vaginal ultrasound______________
- ☐ Hysterectomy and bilateral salpingo-oophorectomy ______________________
- ☐ Chemoprophylaxis ______________________________
- ☐ Other: ______________________________

Colorectal Cancer Coverage Policies

Q9. Do you ever cover any genetic testing related to colorectal cancer for people without cancer?

- o Yes [What is your coverage policy?] ____________________
- o No [Why not?] ____________________

Q10. Do you ever cover any genetic testing related to colorectal cancer for people with cancer?

- o Yes [What is your coverage policy?] ____________________
- o No [Why not?] ____________________

IF Q9 or Q10 = "PRIOR AUTHORIZATION" → Q11
IF Q9 and Q10 = YES and ≠ "PRIOR AUTHORIZATION" → Q12
IF Q2 and Q3 = NO →Q13

Q11. What is the process for prior authorization? ____________________

a) What does the patient have to do to apply for prior authorization?
b) Who makes the final determination?
c) What standards or guidelines, if any, are used in making prior authorization decisions?

Q12. Do you ever cover pre- or post- genetic counseling for MMR testing?

- o Yes [What is your coverage policy?] ____________________
- o No

Q12a. Is pre- and post-genetic counseling a requirement for getting MMR testing?

- o Yes
- o No

Q13. Do you ever cover genetic counseling for patients with increased familial risk of colorectal cancer, without MMR testing?

- o Yes [What is your coverage policy?] ____________________
- o No

IF Q12 or Q13 = YES →Q14
IF Q12 and Q13 = NO → Q15

Q14. Which types of professionals are covered for genetic counseling related to MMR and colorectal cancer? ____________________

Q15. What screening and prophylactic procedures are covered for…

A. MMR Positive patients?

☐ Colonoscopy, FOBT, sygmoidoscopy, or other colorectal screening procedures at younger ages and/or shorter intervals than recommended for people at average risk for colorectal cancer

____

☐ Colectomy or other relevant intestinal surgeries ______________________________

☐ Chemoprophylaxis ______________________________

☐ Other: ______________________________

B. Patients with increased familial risk of colorectal cancer, but had no MMR test, MMR Negative results, or variants of uncertain significance?

☐ Colonoscopy, FOBT, sygmoidoscopy, or other colorectal screening procedures at younger ages and/or shorter intervals than recommended for people at average risk for colorectal cancer

____

☐ Colectomy or other relevant intestinal surgeries ______________________________

☐ Chemoprophylaxis ______________________________

☐ Other: ______________________________

Other Questions

Q16. Are your coverage policies for breast and ovarian cancer screening, genetic testing and counseling, and prophylactic procedures for high-risk patients based on any specific guidelines?

- Breast and ovarian cancer screening

  Yes [Which guidelines?]: ______________________________

  No [How are coverage policies determined?] ______________________________
- Genetic testing and counseling for BOC

  Yes [Which guidelines?]: ______________________________

  No [How are coverage policies determined?] ______________________________
- Prophylactic procedures for high-risk patients

  Yes [Which guidelines?]: ______________________________

  No [How are coverage policies determined?] ______________________________

Q17. Are your coverage policies for colorectal cancer screening, genetic testing and counseling, and prophylactic procedures for high-risk patients based on any specific guidelines?

- Colorectal cancer screening

  Yes [Which guidelines?]: ______________________________

  No [How are coverage policies determined?] ______________________________
- Genetic testing and counseling for CC

  Yes [Which guidelines?]: ______________________________

  No [How are coverage policies determined?] ______________________________
- Prophylactic procedures for high-risk patients

  Yes [Which guidelines?]: ______________________________

No [How are coverage policies determined?] ____________________

IF R = INSURANCE COMPANY → Q21
IF R = SELF-INSURER → Q18, Q19, Q20

Q18. Are there any differences in coverage policies, costs, or reimbursements for people in rural areas? [Ie., coverage for different types of counseling professionals, additional cost reimbursements for travel, or subsidies for out-of-network providers, or an expanded set of procedures allowed to be performed by general practitioners]

- Yes [What are the differences? What plans do we need to gather data for?] ____________________
- No

Q19. Is your insurance plan administered by a health care company, or is it a direct-pay system?

- Administered by HCP [Which company?] ____________________
- Direct-pay system

Q20. Are the policies for your plan determined by corporate offices outside of Oregon?

- Yes [Does the company have an "umbrella" policy that covers all US employees?] ____________________
- No [Who determines the policies for your company insurance plan?] ____________________

IF R = SELF-INSURER → Q22

Q21. Do any of these coverage policies vary across different insurance plans offered by your company? [This is independent of varying co-pays or costs across plans]

- Yes [Identify different plans to gather data for] ____________________
- No

Q22. Do you anticipate any changes being made to your current policies on preventative services related to genetic risk for cancer to comply with the Patient Protection and Affordable Care Act?

- Yes [What changes do you anticipate?] ____________________
- No

END

Comments: ____________________

Appendix B: Resources

Genetic Counseling

What is Genetic Counseling?
Accessed at: http://www.genetichealth.com/Resources_What_Is_Genetic_Counseling.shtml

Genetic Testing
Accessed at: http://www.facingourrisk.org/info_research/hereditary-cancer/genetic-testing/index.php

Genetic Testing: What You Need to Know
Accessed at:
http://www.cancer.org/Cancer/CancerCauses/GeneticsandCancer/GeneticTesting/genetic-testing-benefits-and-drawbacks

Guidelines

U.S Preventive Services Task Force A and B Recommendations
Accessed at: http://www.uspreventiveservicestaskforce.org/uspstf/uspsabrecs.htm

U.S. Preventive Services Task Force Chemoprevention of Breast Cancer
Accessed at: http://www.uspreventiveservicestaskforce.org/uspstf/uspsbrpv.htm

U.S Preventive Services Task Force Genetic Risk Assessment and BRCA Mutation Testing for Breast and Ovarian Cancer Susceptibility
Accessed at: http://www.uspreventiveservicestaskforce.org/uspstf/uspsbrgen.htm

National Comprehensive Cancer Network (NCCN) Guidelines
Accessed at: https://www.nccn.org/professionals/physician_gls/f_guidelines.asp
(Access is free, but log in is required). Once you are registered and logged in, scroll down to the section "NCCN Guidelines for Detection, Prevention, & Risk Reduction", choose:

- Breast Cancer Risk Reduction
- Breast Cancer Screening and Diagnosis
- Colorectal Cancer Screening
- Genetic/Familial High-Risk Assessment: Breast and Ovarian

Patient Protection and Affordable Care Act (PPACA)

How the Affordable Care Act is Helping People with Cancer
Accessed at:
http://www.michigancancer.org/PDFs/AffordableCareAct/AffordableCareActandPeoplewCancer-ACS-091610.pdf

Full text of the Patient Protection and Affordable Care Act can be found at The Library of Congress online.
Accessed at: http://www.gpo.gov/fdsys/pkg/BILLS-111hr3590enr/pdf/BILLS-111hr3590enr.pdf

Protections Against Genetic Discrimination

Your Genetic Information and Your Health Plan – Know The Protections Against Discrimination
Accessed at: http://www.dol.gov/ebsa/publications/gina.html

Genetic Information Nondiscrimination Act Frequently Asked Questions
Accessed at: HTTP://WWW.DNAPOLICY.ORG/GINA/FAQS.HTML

Screening

CDC VitalSigns July 2010 – Cancer Screening: Colorectal Cancer and Breast Cancer
Accessed at: http://www.cdc.gov/vitalsigns/pdf/2010-07-vitalsigns.pdf

The Cancer *You* Can Prevent
Accessed at: http://www.thecanceryoucanprevent.org/

BREAST CANCER AND GENETIC SCREENING
Accessed at: http://www.lbl.gov/Education/ELSI/screening-main.html