

Socioeconomic Status and Interest in Pursuing Genetic Testing for Hereditary Cancer in a US Based  
Population

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**Abstract**

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Cancer is a significant burden to individuals and to the U.S. healthcare system (ACS, 2018). Individuals of low socioeconomic status (SES) have increased mortality and incidence of all types of cancers (Singh & Jemal, 2017). Genetic testing for hereditary cancers can provide information about an individual's risk of developing cancer and guide future screening and preventative services for themselves and their relatives (Sandler, Alfino, & Saleem, 2018). However, there are financial barriers to both meeting with a genetics professional and having genetic testing, particularly for those who make a low income or have limited or no insurance coverage.

This study used the Early Detection of Genetic Risk (EDGE) Study's patient baseline survey to evaluate the relationship between socioeconomic status and interest in pursuing hereditary cancer genetic testing, as well as data from Medicare Coverage Database and genetic testing companies' financial assistance programs (FAPs) to examine what financial assistance exists for individuals pursuing genetic testing. Results showed a strong relationship between all SES and demographic measures and interest in pursuing genetic testing, excluding race and ethnicity. For Medicare to cover the cost of genetic testing for many of the genes, patients must already have symptoms of cancer. Medical and financial criteria a patient must meet to qualify for FAPs is often unclear and inconsistent between companies. If genetic

testing is the future of preventative medicine, more work needs to be done to provide these to low-SES groups and to ensure that those services are used by the most vulnerable populations.

## **Introduction**

Cancer is a significant health burden to individuals and the U.S. health care system. In 2018, 9.5 million people died from cancer (ACS, 2018). This number continues to grow and is expected to reach 16.3 million deaths from cancer per year by 2040. In addition to the number of lives lost to cancer, it also bears a significant financial burden on the healthcare system. It is estimated that \$80.2 billion was spent on cancer care in 2015 in the United States (ACS, 2018).

Cancer disproportionately burdens populations of low socioeconomic status. It is a well-cited fact that in the United States, the poorest individuals have worse health outcomes than the richest. Age-adjusted risk of death is estimated to be two to three times greater in low-SES groups than high-SES groups (Phelan & Link, 2016). This association is stronger for diseases with preventable causes of death, such as cancer.

Individuals in low-SES areas and low-SES income groups have increased mortality and incidence of developing all types of cancers when compared to their high-SES counterparts (Singh & Jemal, 2017). This is true for cancers without strong genetic influences and cancers linked to inherited gene variants. People of low-SES have a 30% increased mortality rate from colorectal cancer compared to their more affluent peers. Similar patterns are seen for prostate and breast cancer mortality, for which individuals of low-SES have a 19% and 6% higher mortality rate, respectively. This pattern is getting worse over time. In the 1950s, individuals of low-SES had 27% lower cancer mortality when compared to individuals of high-SES. Data from 2010-2014 shows that this pattern has reversed, and individuals of low-SES now have a 22% higher cancer mortality rate. Additionally, there remain socioeconomic disparities in survival rates for cancer patients (Singh & Jemal, 2017; Roberts, 2012). These disparities exist even after controlling for cancer stage and tumor grade; cancer patients from low-income neighborhoods have a 56% higher mortality rate than cancer patients from affluent neighborhoods (Singh & Jemal, 2017).

These high rates of cancer largely reflect social determinants of health (SDOH) such as diet, exercise, and substance and tobacco use (Phelan & Link, 2016; Singh & Jemal, 2017). They also reflect access to what Phelan and Link (2016) describe as “flexible resources”. Flexible resources include knowledge,

social capital, and power prestige (Link & Phelan, 2008; Phelan & Link, 2016). These resources shape individual health behaviors so that individuals of higher SES know about, have access to, and can afford more preventative and screening sources (Phelan & Link, 2016). Subsequently there exist huge socioeconomic disparities in the way healthcare is delivered and in the quality of care that individuals receive. There exists a significant need for more access to preventative and screening measures for individuals of low-SES (Singh & Jemal, 2017).

Genetic testing for germline, hereditary cancers in a primary care setting is the future of preventative medicine (Sandler, Alfino, & Saleem, 2018). Genetic testing can be a successful and effective tool for informing individual and familial risk as well as guiding uptake of preventative services. This is reflected in the addition of the topic area 'Genomics' in Healthy People 2020, which aims to increase the evidence supporting the use of genetic testing in guiding clinical decision-making and public health interventions more broadly (HHS, 2020). Genetic testing is recommended at a federal level for understanding a patient's risk of developing breast, ovarian, tubal, peritoneal, and colorectal cancer (HHS, 2020; Owens et al., 2019).

Having information about an individual's risk of developing cancer can guide future screening and preventative services for themselves and their relatives (Sandler, Alfino, & Saleem, 2018). Implementation of these services earlier in a patients' life has the potential to improve the quality of care a patient will receive and reduces the incidence of cancer. For example, individuals found to have pathogenic variants in *BRCA1* or *BRCA2* after genetic testing may have preventative mastectomy or oophorectomy which significantly reduces risk for developing cancer in vulnerable organs. If an individual does not undergo surgery, the quality of care they receive may be improved by undergoing more frequent screening, such as yearly mammograms and breast MRIs. Additionally, once an individual knows their genetic test results, their relatives (who potentially have inherited the same pathogenic variant) may be able to pursue genetic testing. This means not only the individual will be able to uptake preventative screening services, but also at-risk relatives, further reducing the burden of cancer.

While genetic testing can be a successful tool for preventing cancer incidence, there remain significant financial barriers. Healthcare inequalities between the wealthiest and poorest individuals in the United States have continued to rise over the last seventy years (Singh & Jemal, 2017). The National Cancer Institute's website cites the cost of genetic testing itself, if not covered by insurance, as a potential harm to the individual undergoing genetic testing (NCI, n.d.). The out-of-pocket cost of genetic testing can be up to several thousand dollars, depending on the type of test and if their insurance will cover the cost of genetic testing (NIH, 2020).

There is limited research on understanding the financial barriers of genetic counseling and genetic testing (Erwin et al., 2020). However, evidence suggests that both patients and non-genetic providers see cost as a barrier to pursuing genetic testing. Costs associated with the process of accessing genetic services can be a barrier to care. For example, women with low incomes may be less likely to pursue genetic testing for hereditary breast and ovarian cancer because they may have a less flexible work hours and less reliable mode of transportation (Erwin et al., 2020). Therefore, it makes it more difficult for low-SES women to even meet with a genetic counselor and discuss the possibility of genetic testing. Lastly, even after an individual receives a positive genetic variant test result, there are barriers to access of screening and preventative services by SES (Claxton, Sawyer, & Cox, 2019; Singh & Jemal, 2017).

Despite this knowledge, we know next to nothing about interest in pursuing genetic testing amongst individuals of low-SES. Ricker et al. (2006) conducted a needs assessment survey to measure interest in cancer genetic services in an underserved, predominantly Latina cohort from Los Angeles County, California. Ninety percent of the 404 surveyed participants expressed interest in knowing their risk of developing cancer and 85% were motivated to participate in screening and prevention activities. Studies looking at income as a predictor for interest in genetic testing for cancers (conducted 20 or more years ago) have found that income does not predict interest in genetic testing (Sweeny et al., 2014). However, income itself does not fully capture socioeconomic status. Furthermore, research on interest in genetic testing does not adequately describe the relationship between race and SES. Other studies and reviews describe interest in genetic testing stratified by ancestry or geographical location (Cruz-Correa et

al., 2017; Jonassaint et al., 2010). But we still know very little about the relationship between socioeconomic status and interest in pursuing genetic testing.

This study aims to evaluate this relationship and extend the work to not only describe if people of low-SES are interested in pursuing genetic testing but also what factors influence their interest and what barriers they may face. I hypothesize that individuals of low-SES may be just as interested in pursuing genetic testing as individuals of high-SES. I also believe that there are significant financial barriers that prevent people of low-SES to receiving financial assistance in coverage for genetic testing offered by Medicare and through genetic testing companies' financial assistance programs (FAP). The overarching study aims are as follows:

1. Describe the demographic characteristics of the study population,
2. Describe if individuals of low-SES are more or less interested in pursuing genetic testing than individuals of high-SES, and
3. Using publicly available documents, describe the financial and medical criteria an individual must meet in order to receive financial assistance in covering the cost of their genetic testing from genetic testing companies and from Medicare.

## **Methods**

### **The EDGE Study**

This is a smaller project under the Early Detection of GENetic Risk (EDGE) Study. The larger goal of the EDGE Study is to reduce the overall burden of hereditary cancers by implementing cancer risk genomic testing for high-risk individuals in the primary care setting. To accomplish this goal, EDGE is working with one healthcare network in suburban Washington State and one healthcare network in rural Montana and Wyoming. We recruited from twelve clinics, six from each of the healthcare settings. Before the implementation of EDGE, study investigators conducted a patient baseline survey to capture demographics of the intended study population as well as knowledge and beliefs about genetic testing in general. This paper presents data from that baseline survey. Previous research suggests that there may be

geographical differences in interest in and motivations for pursuing genetic testing (Jonassaint et al., 2010). Recruiting from two regionally diverse communities will assist in ensuring our findings will not have any inconsistencies.

### **Patient Baseline Survey**

The patient baseline survey was distributed to patients in participating clinics starting in January 2021, before the implementation of the EDGE program. The purpose of this survey was to gather demographic characteristics, genetic literacy, and attitudes towards genetic testing in general in the intervention's target population.

Socioeconomic measures such as total household income, education level, and type of health insurance were collected in this survey. However, SES is meant to capture an array of resources that an individual has available to them; not just limited to money but also including resources such as access to knowledge, power, and social connections (Phelan & Link, 2016). For this reason, we also included the MacArthur Scale of Subjective Social Status in the survey developed by Nancy Alder and colleagues (Alder & Stewart, 2007) (Appendix 1). The goal of this scale is to measure an individual's perception of their relative position in society. Participants could respond by rating themselves between one and ten.

Other SES and demographic variables measured in the patient baseline survey were age, gender, race, ethnicity, education, insurance, household size, and household income. Age was a free response question, although patients were required to be over the age of 25 to participate. For gender, participants were given the options 'Male', 'Female', 'Other', or 'Prefer not to answer'. If they selected 'Other', they were given a free response option to specify their response. Participants could select as many race options as were applicable, including White, Black or African American, Asian, Native Hawaiian or Pacific Islander, Native American/American Indian/Alaskan Native, or Multiracial. Like gender, participants were also given an 'Other' option which if they selected, they could give a free response to specify. To measure ethnicity, participants were asked if they considered themselves Hispanic and/or Latino.

For education, participants were given seven response options ranging from ‘Less than high school’ to ‘Graduate or professional degree’. Participants were given five response options for insurance, including ‘Commercial’, ‘Government / military insurance’, ‘Medicare’, ‘Medicaid’, or ‘No insurance’. They could select multiple responses here if applicable. For household size, participants could select one option ranging from one to ten or more. Lastly, for income, participants were given the option to select one of seven responses ranging from ‘Less than \$15,000’ to ‘More than \$150,000’. They were also given the option of ‘Prefer not to answer’. To measure interest, I developed a module (Appendix 2) based on a measure published by Desrosiers et al. (2019). This module asked questions about what would influence an individual’s decision to pursue genetic testing and overall interest in genetic testing. Responses were formatted as a five-point Likert scale.

### *Recruitment*

Patients from two healthcare systems (one in Montana and Wyoming and another in Washington state) with six individual clinics were asked to participate in the patient baseline survey. Multivariate analysis was also controlled by healthcare setting to ensure geographical differences were not influencing results. We reached out to a total of 6,588 patients across all twelve clinics – 549 from each clinic. Our original intent was to be able to recruit at least 200 from each clinic. Patients who did not have an email or did not want to complete the survey electronically were mailed a copy of the survey to complete and mail back. Both groups (email and paper copy) received a reminder letter if they had not completed the survey with a link to the survey. Participants were compensated with a \$10 Tango gift card for completing the survey.

### *Data Analysis*

Data from the patient baseline survey was analyzed in SPSS. Demographic variables were checked for outliers and data was cleaned when necessary. When finding median for age, I removed three outliers that were likely due to mistakes in data entry. Missing values were not replaced. I used

descriptive statistics to describe income, education level, health insurance, MacArthur scale, and race for our population of interest (Table 1).

To run bivariate analyses, I created a new interest variable that was an average of five interest survey items. Before making the average, I ran a reliability check to ensure consistency which returned a Chronbach's alpha value of 0.882. I then ran bivariate analyses looking at average or overall interest and each individual demographic variable and indicator of SES. Because my new combined interest variable had an irregular distribution, with the median of four out of the five-point Likert scale, I split this variable into a binary variable where people with averages of four and more were grouped together and anyone reporting a value below four was grouped together.

For further analysis, I also recoded all demographic and SES variables. 'Prefer not to answer' responses were excluded from analysis. If a case did not include one of the variables included in analysis, the case was excluded. For gender, I ran a Pearson's chi-square test comparing male and female responses. 'Other' gender responses ( $n = 3$ ) were excluded from analysis because there were so few. For the same reason, race and ethnicity were combined into one variable, so that White, non-Hispanic participants represented one group ( $n = 1,804$ ) and non-White and/or non-Hispanic participants represented the second ( $n = 208$ ). Education groups were split at those who had received at least an associate degree or higher ( $n = 1,431$ ) and those who had received some post-high school training or less ( $n = 784$ ). Insurance was split between those who had commercial insurance ( $n = 1,378$ ) and those who only had Government/military insurance, Medicare, Medicaid, or no insurance ( $n = 836$ ). Participants who had both commercial insurance and other forms of insurance were only counted as having commercial insurance. Individuals who reported a household size of two or less were grouped ( $n = 1,515$ ) and individuals reporting three or more were grouped ( $n = 571$ ). For household income, individuals making less than \$74,999 were grouped ( $n = 957$ ) and individuals making at least \$75,000 were grouped together ( $n = 1,243$ ). Lastly, MacArthur Scale of Subjective Social Status responses were split so that

individuals scoring six or higher were grouped together (n = 1,453) and those scoring five or below were grouped (n = 728).

Before running more analysis, all independent variables were reviewed for multicollinearity by running logistic regression between all variables, and none was detected. I then ran a binary logistic regression to assess the relationship between all SES and demographic variables and interest in pursuing genetic testing. After running my multivariate analysis with all variables, I explored multivariate analyses with indicators with the strongest relationship to interest in pursuing genetic testing to reduce the degrees of freedom in my analysis and examine the relationship between my outcome variable and the most relevant independent variables. First, I ran multivariate analysis with age and gender alone, then I added education and income.

## **Medicare Database**

The Medicare Coverage Database contains many documents that describe when Medicare will cover the cost of medical services for patients and how providers should bill for these visits. For the first round of coding, I searched for keywords related to the 31 genes and 14 hereditary cancers and cancer syndromes that EDGE will be testing high-risk participants for (See Appendix 3 for genes and search terms). These genes were selected because they are the genes that Color tests for on their hereditary cancer panel. My search was restricted to the following document types: National Coverage Analysis (NCA), National Coverage Determinations (NCDs), Medicare Coverage Documents (MCDs), final (as opposed to proposed) Local Coverage Determinations (LCDs), and Billing and Coding Articles (Center for Medicare & Medicaid Services, n.d.). Coverage determination documents were the most relevant to this work because they describe the medical criteria an individual must meet in order to have the cost of a medical service paid for Medicare. Articles were gathered from my search, but were not analyzed in full depth as they describe how a provider should bill a medical service. A limitation to this search was that an LCD or Local Coverage Article (LCA) must be active for one of the states in which the EDGE Study

takes place (Washington, Montana, or Wyoming). Noridian is Medicare's contractor for Washington state and Wisconsin Physicians Service Insurance Corporation (WPSIC) is Medicare's contractor for Montana and Wyoming. Articles that were "closed" or "retired" were not considered.

In the second round of coding, I read the returned LCDs in order to determine if they were applicable to my exclusion criteria. LCDs were not considered if, upon further investigation, they did not describe criteria for coverage of germline genetic testing. This excluded testing for genetic expression or methylation as well as testing of cancer tissue. If an LCD met these eligibility criteria, I read further to determine what criteria an individual must meet to have the cost of their genetic test covered by Medicare. All LCDs were archived in May 2021.

### **Financial Assistance Programs**

Information about financial assistance programs (FAP) was gathered from six genetic testing companies' (Ambry Genetics, Prevention Genetics, Myriad, Invitae, Color, and Blueprint Genetics) websites. All relevant information and resources were gathered, including: general website language, blog posts, applications for financial assistance, and any additional PDFs that described the medical or financial criteria an individual must meet in order to have the cost of their genetic testing reduced if and when provided (Table 5). If I could not find detailed information on their website describing these criteria, I reached out to their customer service team to attempt to gather more information. All materials were archived in April 2021. These materials were then read in detail for relevant information that describes specific criteria or specific costs a patient should expect when applying for financial assistance. Findings from FAPs were then sorted by genetic testing company and by medical criteria, financial criteria, and expected cost to patient.

## **Results**

### **Socioeconomic Status is a Significant Bivariate Predictor for Interest**

Two thousand two hundred and forty-four people completed the patient baseline clinic, with 1,301 coming from Billings Clinic and 943 coming from MultiCare Health System (Appendix 3). The median age of all participants was 61 years with a standard deviation of approximately 15 (Table 1). Sixty-one percent of participants identified as female and 31% as male. Participants were given the option to select multiple responses for race, if applicable. The majority (approximately 89%) of participants identified as White and Not Hispanic or Latino. Three percent identified as Asian, 2% identified as Black or African American, and 2% identified as Native American/American Indian/Alaskan Native.

Most participants were at least high school graduates, with only 3% of our study population falling below this education line. Twenty percent of participants had received a Graduate or professional degree. Most participants had a household size between one and two individuals (n = 1,515). Results show a fairly even distribution for household income, with the minority of participants making less than \$25,000 a year (n = 106). While 61% of participants indicated that they had commercial/private insurance (n = 1,378), nearly half of participants reported having Medicare or Medicare supplement (n = 1,015). An additional 18% had either government/military insurance, Medicaid, or no insurance (n = 417). Lastly, for the MacArthur Scale of Subjective Social Status, most participants considered themselves between a five or seven (n = 1,297). A smaller amount rated themselves as eight or higher (n = 547) and an even smaller amount rated themselves four or below (n = 337).

Chi-square tests comparing overall interest with individual demographic and SES variables revealed most relationships as statistically significant, except for race and ethnicity (Table 2). Comparing age, gender, and household size to overall interest resulted in significance values of  $p < 0.001$ . Those who are less than 65 years old, female, and live in a household size of greater than two are much more likely to be interested in genetic testing than their counterparts. Insurance, education, MacArthur Scale of Subjective Social Status, and household income also returned p-values less than 0.05. Participants with commercial insurance, higher levels of education, higher incomes, and lower ratings on the subjective social scale were more likely to be interested in genetic testing. Race and ethnicity was near significance with a p-value of 0.110.

Multivariate analysis of combined interest and all SES and demographic variables revealed that only age and gender were significant variables influencing an individual's interest in pursuing genetic testing with p-values < 0.001 (Table 3). To follow, I ran multivariate analysis with age and gender alone, which returned very strong p-values < 0.001 (Table 4). Education combined with gender and age was statistically significant at p = 0.002. Income was also statistically significant at p = 0.036. Other variables added to this analysis in this way did not return significant results.

### **Medicare Database Medical Criteria is Inconsistent Among Different Cancers and Genetic Tests**

My search of 31 genes and 14 cancer syndromes returned a total of 16 unique LCDs, 29 unique LCAs, and one NCA (Appendix 4 and Appendix 5). Many LCDs, LCAs, and NCAs appeared twice when searching for different genes. Appendix 4 also shows when a search returned no results. In my second-round coding, four of the sixteen LCDs (MoIDX: NRAS Genetic Testing for Noridian and WISPC and MoIDX: Decision Dx-UM for Noridian and WISPC) were excluded because they only discussed coverage of genetic testing of tumor tissue. The remaining twelve LCDs all discussed the medical criteria a patient must meet for Medicare to cover the cost of germline genetic testing.

LCDs from the two contractors (Noridian and WISPC) that discussed genetic testing for the same genes or cancer disorder were identical in content. Many of the genetic tests discussed by these LCDs are not covered by Medicare unless a patient is already shown signs or symptoms of cancer (Appendix 6). This is true for *BRCA1*, *BRCA2*, and genes associated with Lynch syndrome (such as *MLH1*). In order to have the cost of genetic testing for Lynch syndrome covered for a patient, clinicians must follow a step-by-step approach. First, they are to test for microsatellite instability (MSI) and immunohistochemistry (IHC) in the tumor tissue, followed by the *BRAF* variant if suggestive of *MLH1*, then targeted gene testing as informed by the IHC findings. Genetic testing for specific familial pathogenic variants is only considered medically necessary when a patient has symptoms of cancer.

For MoIDX: Next-Generations Sequencing for Myeloid Malignancies (both Noridian and WISPC), genetic testing can be performed before a patient is diagnosed with cancer but they must have an

undefined cytopenia for more than four months. LCDs for melanoma risk stratification indicate that genetic testing is appropriate for individuals with a personal history of melanoma who have reached a certain stage of cancer or undergoing workup and being evaluated for treatment. More general terminology also stated that genetic testing would be considered “reasonable and necessary where it has both shown an ability to enhance risk stratification and where this risk stratification may be used to select among a number of different consensus recommended management approaches.” If a clinician can prove clinical utility, their patient may meet the criteria of having the cost covered by Medicare.

*APC* and *MUTYH* genetic testing LCDs require that a patient have a history of familial adenomatous polyposis (FAP), attenuated FAP, or MYH-associated polyposis and a personal history of 20 or more adenomas over a lifetime.

The last two LCDs describe the criteria Medicare must meet in order to have the cost of repeat germline testing covered for each Medicare contractor. It states the repeat testing may be considered when there is established clinical utility presented in the remaining genes in the test. For example, if a patient already had genetic testing for *BRCA1* but wanted to pursue genetic testing of other genes associated with breast and ovarian cancer, they would fall into the category of repeat testing because *BRCA1* is on panel tests for hereditary breast and ovarian cancer. However, clinicians are advised to be sure that the test they are ordering is covered by other LCDs and that it is not a duplicate test that the patient has already completed.

Six of the LCDs describe the required documentation that a clinician must submit to Medicare (Appendix 7). For *BRCA1* and *BRCA2* genetic testing (for both Noridian and WISPC), clinicians must submit documentation from the patient’s medical record such as relevant medical history, physical examinations, and diagnostic results or procedures that support the medical necessity of genetic testing. For Lynch syndrome, clinicians are required to submit “sufficient clinical and family history to warrant first time testing.” They are directed to provide enough information for labs to make the appropriate selection of target genes for each patient. In the LCD for next-generation sequencing for myeloid malignancies, it is requested that clinicians submit additional information to ensure the contractor

understands what test is being performed and why; although, they do not provide any detail on what the additional information should include.

### **Financial Assistance Programs Reduce Barriers Dependent on Household Size and Income**

Of the six genetic testing companies, all stated on their website that they had a financial assistance program, although the amount and type of information provided on FAPs varied greatly between companies (Table 5). Three companies – Invitae, Myriad, and Ambry – provided an application for the FAP that described exactly how much a patient should expect to be discounted from the total cost of their genetic test based off of their income and household size. Companies that did not include an application instructed providers to email the company if they have a patient who they believe would be eligible. Two genetic testing companies provided additional materials with information about financial and medical criteria an individual must meet to qualify for financial assistance. Myriad provided two additional PDFs, one which specifically described the financial criteria and one which specifically described medical criteria. Ambry provided one additional PDF describing which insurances they are contracted with so patients can see if their insurance will assist in covering the cost of genetic testing.

#### *Medical Criteria for Genetic Testing Companies' FAPs*

Only two companies describe what medical criteria an individual must meet in order to qualify for genetic testing in detail. On Color's website, they described their program where if a patient has a first degree relative with a pathogenic variant, they offer genetic testing for \$50. To qualify, patients must provide their relative's positive genetic test results. If Color tests for the pathogenic variant in the gene identified in the relative, they will review their application and send them a promotional code to reduce the cost of that genetic test to fifty dollars.

Myriad described the medical criteria for qualifying for their FAP in detail by type of cancer. These criteria are based on National Comprehensive Cancer Network (NCCN) screening guidelines (NCCN, 2021). If a patient meets clinical diagnostic criteria for Li-Fraumeni Syndrome, *PTEN*

Hamartoma Tumor Syndrome, Hereditary Diffuse Gastric Cancer Syndrome, or Juvenile Polyposis Syndrome, they meet the medical eligibility criteria. Additionally, patients are eligible when they need genetic testing and are diagnosed with breast cancer and/or ovarian cancer (at any age), metastatic prostate cancer (age not defined), young colorectal cancer (patient is 64 years old or younger), young endometrial cancer (patient is 64 years old or younger), ovarian cancer (age not defined), or pancreatic cancer (age not defined). Myriad fully covers the cost of single site genetic testing when a patient has a known familial variant of a specific subset of cancer genes or when guidelines recommend that Ashkenazi Jewish and Central/Eastern European patients have multisite testing for one of the three founder variants.

#### *Financial Criteria for Genetic Testing Companies' FAPs*

All six genetic testing companies described the financial criteria an individual should meet in varying detail. For all companies, this was based off the Department of Health and Human Services (HHS) federal poverty lines, household income, and household size. Ambry Genetics provided a cost calculator, in which patients input their household size, insurance type, household income, and state to determine what their expected out-of-pocket cost for genetic testing would be. They also stated on their website that the average cost a patient pays out-of-pocket is around one hundred dollars. Myriad provided a table that described exactly how much a patient should expect to pay for their genetic testing dependent on their income and family size. If a patient's income is up to two-times the federal poverty line (as defined by HHS), they should expect to pay zero dollars out of pocket. If a patient's income is three times the federal poverty line, they should expect to pay one hundred dollars. If a patient's income is four times the federal poverty line, they should expect to pay two hundred and ninety-five dollars.

Invitae provides two tables on their financial aid application that help patients and providers understand what out-of-pocket cost they should expect to pay: one for patients without insurance and one for patients with insurances. For patients without insurance, Invitae lists the incomes and household size an individual must have in order to have the entire cost of the genetic test waived. For an individual with a household size of one, they must make less than approximately \$76,000 a year. For an individual with a

household size of eight or greater, they must make less than approximately \$264,000 in combined income to have the cost of their test waived.

For patients with insurance, these incomes are considerably lower. For a patient with insurance and with a household size of one, they must make less than \$12,740 a year to have the entire cost of their genetic testing waived. For patients with a household size of eight or greater, they must make less than \$44,120 a year. In the same table, Invitae also describes what household size and income requirement an individual must meet to receive an 80%, 60%, or 40% discount for their genetic testing. Of note, income levels and household sizes for patients with insurance to receive a 40% discount are the same for patients without insurance to receive a full discount. Additionally, patients with Medicare and other government-funded health insurances are asked not to use Invitae's application form but to submit their insurance information for Invitae to bill the plan directly, if appropriate. Lastly, although the tables inform patients what discount they should expect, the application does not explicitly state the cost of testing. On their website, they list the cost of diagnostic testing as two hundred and fifty dollars.

Blueprint Genetics also provided two tables on their website to help patients understand what they should expect to pay out of pocket. Out-of-pocket prices vary depending on whether patients are 200%, 400%, or 600% above the federal poverty line. Single gene, panels, and whole exome sequencing (for one patient) range from \$250 for patients who make up to two times the federal poverty line for their household size to \$350 for patients who make up to six times the federal poverty line. Familial and targeted variant testing ranges from \$50 to \$90.

Prevention Genetics is less descriptive about what financial criteria an individual must meet. On their website, they describe their Financial Hardship Program and state that they have set aside funds to help patients who need financial assistance. However, there is no application and providers are instructed to email the company if they believe they have an eligible patient. Patients are awarded financial assistance on a case-by-case basis.

As described in the medical criteria, Color offers discounted genetic testing for family members of patients with known pathogenic variants. If a patient can provide the positive genetic test results of a

first-degree relative, they will pay \$50 for genetic testing of the same variant. It is unclear whether this would apply to both larger panel tests and single gene analyses. Additionally, Color has a financial assistance program titled 'Color for All' that partners with research hospitals and clinics to provide discounted genetic testing for eligible participants. However, they do not describe what criteria an individual must meet to be eligible for this program on their website. When contacted for more information, Color instructed me to reach out to the research clinics for more information.

All six genetic testing companies reported that they provided financial assistance for patients without insurance, who were not able to pay the full cost of their genetic test. Decisions about level of financial assistance is largely made based on a patient's household size and income relative to the HHS's federal poverty line. Depending on which company a patient is tested through, they may be eligible for some level of financial assistance if they make up to six times the federal poverty line. If patients are eligible for FAPs, they should expect to pay anywhere from \$0 to \$350 for the cost of their genetic test. The cost of genetic testing varies by company, even for individuals with the same income and household size. If a patient has Medicare, they are not eligible for FAPs; rather, the cost for testing will be billed to their insurance.

## **Discussion**

This project aimed to look at the relationship between SES and interest in pursuing genetic testing for hereditary cancers. This was accomplished through collecting and analyzing data in our patient baseline survey. Additionally, I aimed to tie these to real world assistance that exists for participants who are interested in pursuing genetic testing. This was achieved by executing an in-depth analysis of Medicare's Coverage Database and Financial Assistance Programs offered by genetic testing companies.

I hypothesized that there would be no significant difference in interest in pursuing genetic testing for individuals of low-SES and high-SES. My bivariate analysis showed that for nearly every variable, there were differences in interest in genetic testing. However, for some indicators individuals of low SES were more likely to be interested in genetic testing and for other indicators individuals of high SES were

more likely to be interested in genetic testing. For example, individuals who rated themselves lower on the MacArthur Scale of Subjective Social Status were more interested in pursuing genetic testing while the same was true for individuals with higher incomes. Multivariate analysis also showed that individuals of both a higher education and a higher income bracket (under 65 years old) combined were much more interested in pursuing genetic testing.

Given the results of this analysis, it may be possible that individuals of higher-SES may be more interested in cancer genetic testing because they perceive less barriers to genetic testing. Additionally, although this survey used MacArthur Scale of Subjective Status in an effort to capture a full picture of SES, it was not significant in any of the multivariate analysis. SES remains a difficult concept to measure; although indicators like income, education, and subjective social status are clearly related, no single variable paints a full picture of SES.

Still, for individuals who make a lower income and have no insurance or Medicare, there exist financial barriers to genetic testing. Many of the 31 genes EDGE is testing for cancer do not have any information about coverage posted in the Medicare Coverage Database. If there is no policy for a particular test, then we don't know whether Medicare will cover the cost of genetic testing and they won't decide until after the test is done. That means that patients may be expected to pay for the full cost of genetic testing.

Among those that do have information posted in the Medicare Coverage Database, available resources that describe when and if a patient can receive financial assistance in paying for their genetic testing are inconsistent. Most LCDs only cover the cost of genetic testing for cancers after a patient is already displaying symptoms. This does little to nothing for preventing cancer, which should be the primary goal of genetic testing. Closer analysis of LCDs also showed that there was no uniformity in required documentation or eligibility criteria. If a provider has a patient who wants genetic testing, they will have to find the specific LCD for the gene or cancer syndrome they are testing for to decipher if they need to submit additional materials and what those materials should be.

Financial Assistance Programs from genetic testing companies were similar to Medicare documentation in that they were not uniform or consistent. The amount of information publicly available about FAPs was extremely varied between genetic testing companies; some only posted on their website that there was financial assistance available and to inquire for more details while others provided PDFs with specific medical and financial criteria a patient must meet. Most companies do not explicitly state what medical criteria a patient must meet to qualify for financial assistance, although most mention that there are medical criteria on their website. Additionally, genetic testing is a lengthy process. If a patient and/or provider decides they would like to apply for a genetic testing company's FAP, this may add time to the testing process that could negatively influence access to care and future preventative services.

Possibly most importantly, Medicare patients are not eligible for FAPs. This, in combination with limited coverage described in LCDs leaves Medicare patients in an extremely vulnerable position where they may be expected to pay a large sum out of pocket if they wish to pursue genetic testing for preventative care.

One major limitation to this project was the racial and ethnic diversity of the study population. Eighty-nine percent of our study population identified as white and 88% identified as Non-Hispanic or Latino. It was my original intention to see if the effects I would find in my bivariate and multivariate analysis were even more drastic for non-White participants. As with every other health outcome that disproportionately impacts individuals of low-SES and non-White individuals, it is important to consider the contribution of race and how it may impact interest in pursuing genetic testing. Further work with a different study population would need to be done to investigate this relationship. Additionally, approximately 40 paper surveys were not included in this analysis due to time constraints. Other limitations include a low response rate to our survey (which was around 34%) and the geographical focus. As previously mentioned, we attempted to control for geographical differences in our analysis but only used clinics from two geographically distinct areas.

Lastly, understanding interest in genetic testing is significant because it could ultimately influence whether an individual will decide to pursue genetic testing. In Ajzen's theory of planned

behavior (Ajzen, 2002), an attitude towards a behavior is a large contributor to the formation of a behavioral intention. While there is limited research that demonstrates this relationship with genetic testing, there is some evidence to support the relationship between interest and uptake in genetic testing. For example, in a study that looked at genetic testing interest and uptake in genetic testing for patients with lung cancer, it was found that participants who said they ‘definitely would’ take a genetic test were more likely to take a genetic test (Sanderson et al., 2010). However, this effect was modest and more research supporting this relationship needs to be conducted to back this claim.

## **Conclusion**

If genetic testing for hereditary cancers is to become the future of preventative medicine, it is necessary that it first becomes more accessible to individuals of low-SES. This is particularly paramount given that individuals of low-SES have higher cancer incidence and mortality. Future work investigating this relationship should look at SES and uptake in genetic testing when it is offered as a free service. Additional work could investigate the relationship between interest in pursuing genetic testing and uptake. This is a largely understudied area, and although there are theoretical models that support this relationship, research has shown mixed results. Altogether, major financial barriers exist that perpetuate poor health outcomes between the poorest and the richest individuals in the United States. More work needs to be done to provide preventative health service to low-SES groups and to ensure that those services are used by the most vulnerable, relevant groups.

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## Tables

**Table 1: Characteristic of the Patient Baseline Survey Participants**

<b>Table 1. Characteristics of the Patient Baseline Survey Participants</b>		
<b>Characteristics</b>	<b>Study Participants (n = 2244)</b>	
	<b>No. of Participants</b>	<b>%</b>
<b>Age, years</b>		
Median (SD)	61 (15.2)	-
<b>Gender</b>		
Male	822	37%
Female	1380	61%
Other	3	0%
<b>Race*</b>		
White	2007	89%
Black or African American	34	2%
Asian	59	3%
Native Hawaiian or other Pacific Islander	5	0%
Native American/American Indian/Alaskan Native	38	2%
Multiracial	27	1%
Other	18	1%
Prefer not to answer	55	2%
<b>Ethnicity</b>		
Not Hispanic or Latino	1979	88%
Hispanic or Latino	55	2%
Prefer not to answer	80	4%
<b>Education</b>		
Less than high school (less than 9th grade)	17	1%
Some high school (9th to 12th grade), no diploma	44	2%
High school graduate (diploma or GED or equivalent)	252	11%
Some post-high school training (college or occupational, technical, or vocational training), no degree or certificate	471	21%
Associate (2-year) college degree, or completed occupational, technical, or vocational program and received degree or certificate	331	15%
Bachelor's degree (for example: BA, AB, BS)	642	29%
Graduate or professional degree (for example: MA, MBA, JA, MD, PhD)	458	20%
<b>Insurance*</b>		

Commercial (private) insurance (for example Premera, Regence, Blue Cross / Blue Shield, Marketplace)	1378	61%
Government / military insurance (for example: VA, Indian Health Service)	186	8%
Medicare (for example: Medicare Advantage)	1015	45%
Medicaid (for example: Apple Health)	184	8%
None	47	2%
<b>Household Size**</b>		
One	432	19%
Two	1083	48%
Three	257	11%
Four or more	314	14%
<b>Household Income</b>		
Less than \$15,000	106	5%
Between \$15,000 and \$24,999	162	7%
Between \$25,000 and \$49,999	317	14%
Between \$50,000 and \$74,999	372	17%
Between \$75,000 and \$99,999	333	15%
Between \$100,000 and \$149,999	323	14%
More than \$150,000	258	11%
Prefer not to answer	329	15%
<b>MacArthur Scale of Subjective Social Status**</b>		
One through four	337	15%
Five	391	17%
Six	435	19%
Seven	471	21%
Eight through ten	547	24%
* Participants had the option to select more than one response. Participants who selected more than response were counted for each box they checked.		
** Participants were given the selection one through ten on the survey, but responses have been grouped for analytic purposes		

**Table 2: Interest and SES Bivariate Analysis**

<b>Table 2. Bivariate analysis</b>				
	<b>Low Interest (&lt;4)</b>	<b>High Interest (&gt;=4)</b>	<b>Chi-Square</b>	<b>p-value</b>
<b>Age**</b>	861	1119	34.552	0.000
<b>Gender**</b>	937	1256	37.258	0.000
<b>Race and Ethnicity</b>	827	1179	2.559	0.110

<b>Education*</b>	942	1266	8.714	0.003
<b>Insurance*</b>	940	1267	3.890	0.049
<b>Household Size**</b>	878	1200	10.684	0.001
<b>Household Income*</b>	933	1259	4.299	0.038
<b>MacArthur Scale of Subjective Social Status*</b>	922	1254	5.733	0.017
* Statistically significant, where $p < 0.05$				
** Statistically Significant, where $p < 0.001$				

**Table 3: Multivariate Analysis of Interest and all SES/Demographic Variables**

<b>Table 3. Multivariate Analysis of Interest and all SES/Demographic Variables</b>			
	<b>B</b>	<b>S.E.</b>	<b>Sig.</b>
<i>Overall interest in genetic testing (greater than or equal to four versus less than four)</i>			
<b>Age**</b>	0.409	0.117	0.000
<b>Gender**</b>	-0.458	0.107	0.000
<b>Race and Ethnicity</b>	0.067	0.183	0.712
<b>Education</b>	0.213	0.112	0.057
<b>Insurance</b>	-0.101	0.113	0.371
<b>Household Size</b>	-0.106	0.125	0.397
<b>Household Income</b>	0.185	0.117	0.112
<b>MacArthur Scale of Subjective Social Status</b>	-0.16	0.123	0.192
* Statistically significant, where $p < 0.05$			
** Statistically Significant, where $p < 0.001$			

**Table 4: Multivariate Analysis of Most Significant Indicators of SES**

<b>Table 4. Multivariate Analysis of Most Significant Indicators of SES</b>									
	<b>B</b>	<b>S.E.</b>	<b>Sig.</b>	<b>B</b>	<b>S.E.</b>	<b>Sig.</b>	<b>B</b>	<b>S.E.</b>	<b>Sig.</b>
<i>Overall interest in genetic testing (greater than or equal to four versus less than four)</i>									
<b>Age**</b>	-0.477	0.093	< 0.001	-0.473	0.094	< 0.001	-0.479	0.095	< 0.001
<b>Gender**</b>	0.48	0.096	< 0.001	0.493	0.096	< 0.001	0.514	0.098	< 0.001
<b>Education**/*</b>	-	-	-	-0.308	0.097	0.002	-0.258	0.101	0.011
<b>Household Income *</b>	-	-	-	-	-	-	-0.207	0.099	0.036
<p>* Statistically significant, where <math>p &lt; 0.05</math>  ** Statistically Significant, where <math>p &lt; 0.001</math></p>									

**Table 5: Genetic Testing Companies' Resources with Information on Financial Assistance Programs**

<b>Genetic Testing Company</b>	<b>Medical Criteria</b>	<b>Financial Criteria</b>
<b>Blueprint Genetics</b>	Not described	Website Language
<b>Color</b>	Website Language	Website Language
<b>Invitae</b>	Not described	Website Language FAP Application
<b>Myriad</b>	Website Language Medical Criteria PDF	Website Language Financial Criteria PDF FAP Application
<b>Prevention Genetics</b>	Not described	Website Language
<b>Ambry</b>	Not described	Website Language FAP Application Payers by Region PDF

## Appendices

### Appendix 1: MacArthur Scale of Subjective Social Status

**79. Think of this ladder as representing where people stand in the United States.**

At the **top** of the ladder (10) are the people who are the best off – those who have the most money, the most education and the most respected jobs. At the **bottom** (1) are the people who are the worst off – who have the least money, least education, and the least respected jobs or no job. The higher up you are on this ladder, the closer you are to the people at the very top; the lower you are, the closer you are to the people at the very bottom.

**Where would you place yourself on this ladder?**

Select a number 1 – 10 (1 representing people who are the worst off and 10 people who are the best off) on the ladder where you think you stand at this time in your life, relative to other people in the United States.

- 10
- 9
- 8
- 7
- 6
- 5
- 4
- 3
- 2
- 1



### Appendix 2: Interest in Pursuing Genetic Testing

Everyone has some risk of developing cancer. Cancer is usually caused by gene mutations that happen randomly, but sometimes the mutation is hereditary (passed from a parent to their child). People who carry a hereditary mutation do not always get cancer, but their risk is higher than average.

1. How many first-degree relatives do you have? (First-degree relatives are those directly related to you – your parents, children, and siblings.)

\_\_\_\_\_

2. How many of your first-degree relatives have had genetic testing for cancer?

\_\_\_\_\_

3. Have you ever had genetic testing for cancer?

- Yes
- No
- Uncertain

4. How many of your first-degree relatives have had cancer?

\_\_\_\_\_

5. Have you ever had cancer?

- Yes
- No
- Uncertain

6. How many of your first-degree relatives have died from cancer?

\_\_\_\_\_

7. If your personal and familial history suggested you were at high risk for cancer, how interested would you be in having genetic testing?

- |                       |                         |                       |                       |                       |
|-----------------------|-------------------------|-----------------------|-----------------------|-----------------------|
| Not at all interested | A little bit interested | Moderately interested | Very interested       | Extremely interested  |
| <input type="radio"/> | <input type="radio"/>   | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Below is a list of reasons someone might give for having genetic testing for hereditary cancer. For each item, please indicate if you see it as a reason to have genetic testing, with 1=strongly disagree and 5=strongly agree.

I would get genetic testing to...

	<u>Strongly Disagree</u>	<u>Disagree</u>	<u>Uncertain</u>	<u>Agree</u>	<u>Strongly Agree</u>
8. Provide reassurance that I will not get cancer.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Establish my personal risk of developing cancer.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Determine whether more frequent / different cancer prevention	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

measures could reduce my personal risk of developing cancer.					
11. Help my family members understand their risk of developing cancer.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Determine whether my family members should have genetic testing.					
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please indicate whether each of the following statements would make you more likely to have genetic testing for hereditary cancer, with 1=strongly disagree and 5=strongly agree.

I would be interested in genetic testing if...

	<u>Strongly Disagree</u>	<u>Disagree</u>	<u>Uncertain</u>	<u>Agree</u>	<u>Strongly Agree</u>
13. My doctor recommended it.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. The information might affect my health.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. The information might affect my family member's health.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. The test was free/low cost.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

17. Please share any thoughts you have about reasons for or against having genetic testing.

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**Appendix 3: Medicare Database Search Terms**

<u>Group Name</u>	<u>Genes Included</u>	<u>Search term</u>
Breast and Ovarian Cancer	<i>BRCA1</i>	"brca1" "brca1 genetic" "brca1 gene"

	<i>BRCA2</i>	"brca2" "brca2 genetic" "brca2 gene"
	<i>PALB2</i>	"palb2" "palb2 genetic" "palb2 gene"
	<i>ATM</i>	"atm" "atm genetic" "atm gene"
	<i>NBN</i>	"nbn genetic" "nbn gene"
Additional Searches		"brca genetic" "breast cancer genetic" "breast cancer"
Ovarian	<i>BRIP1</i>	"brip1" "brip1 genetic" "brip1 gene"
	<i>RAD51C</i>	"rad51c genetic" "rad51c gene"
	<i>RAD51D</i>	"rad51d genetic" "rad51d gene"

Additional Searches		"ovarian cancer" "ovarian cancer genetic" "ovarian cancer gene"
Li- Fraumeni	<i>TP53</i>	"tp53" "tp53 genetic" "tp53 gene"
Additional Searches		"Li Fraumeni genetic" "Li Fraumeni"
Breast and Gastric	<i>CDH1</i>	"cdh1" "cdh1 genetic" "cdhi gene"
Additional Searches		"Gastric cancer genetic" "Gastric Cancer"
Colon (Lynch)	<i>MLH1</i>	"mlh1" "mlh1 genetic" mlh1 gene"
	<i>MSH2</i>	"msh2" "msh2 genetic" "msh2 gene"
	<i>MSH6</i>	"msh6" "msh6 genetic" "msh6 gene"
	<i>PMS2</i>	"pms2" "pms2 genetic" "pms2 gene"

	<i>EPCAM</i>	"epcam" "epcam genetic" "epcam gene"
Additional Searches		"colon cancer" "colon cancer genetic" "Lynch syndrome"
Breast and Endometrial	<i>PTEN</i>	"pten" "pten genetic" "pten gene"
Additional Searches		"Uterine cancer" "uterine cancer genetic"
Breast and Colon	<i>CHEK2</i>	"chek2" "chek2 genetic" "chek2 gene"
Breast	<i>BARD1</i>	"bard1" "bard1 genetic" "bard1 gene"
Breast	<i>NF1</i>	"nf1" "nf1 genetic" "nf1 gene"
Colon	<i>APC</i>	"apc" "apc genetic" "apc gene"

Colon (Juvenile Polyposis Syndrome)	<i>BMPRI1A</i>	"bmpr1a" "bmpr1a genetic" "bmpr1a gene"
	<i>SMAD4</i>	"smad4" "smad4 genetic" "smad4 gene"
Additional Searches		"Juvenile Polyposis Syndrome"
Colon (Adenomatous Polyposis)	<i>GREM1</i>	"grem1" "grem1 genetic" "grem1 gene"
	<i>POLD1</i>	"pold1" "pold1 genetic" "pold1 gene"
	<i>POLE</i>	"pole" "pole genetic" "pole gene"
Additional Searches		"Adenomatous Polyposis"
Colon (MUTYH-Associated Polyposis)	<i>MUTYH</i>	"MUTYH" "MUTYH genetic" "MUTYH gene"
Additional Searches		"MUTYH-Associated Polyposis"
Colon (Peutz-Jeghers Syndrome)	<i>STK11</i>	"stk11" "stk11 genetic" "stk11 gene"

Additional Searches		"Peutz-Jeghers Syndrome"
Pancreatic	<i>CDKN2A</i>	"cdkn2a" "cdkn2a genetic" "cdkn2a gene"
Additional Searches		"pancreatic cancer" "pancreatic cancer genetic"
Malignant Pleural Mesothelioma	<i>BAP1</i>	"bap1" "bap1 genetic" "bap1 gene"
Additional Searches		"Malignant Pleural Mesothelioma"
Melanoma	<i>CDK4</i>	"cdk4" "cdk4 genetic" "cdk4 gene"
	<i>MITF</i>	"mitf" "mitf genetic" "mitf gene"
Additional Searches		"melanoma"

## Appendix 4: Medicare Database Search Results

Group Name	Genes Included	LCDs	LCAs
Breast and Ovarian Cancer	<i>BRCA1</i>	L36163 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing L36813 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing	A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Tesing A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A55295 - Billing and Coding: MoIDX: Myriad's BRCAnalysis CDx A55224 - Billing and Coding: MoIDX: Myriad's BRCAnalysis CDx A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes
	<i>BRCA2</i>	L36163 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing L36813 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing	A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Tesing A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A55295 - Billing and Coding: MoIDX: Myriad's BRCAnalysis CDx A55224 - Billing and Coding: MoIDX: Myriad's BRCAnalysis CDx A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes
	PALB2	No results	A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Tesing A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes
	<i>ATM</i>	No results	A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Tesing A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)
	<i>NBN</i>	No results	No results

Additional Searches		L36163 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing L36813 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing L38353 - MoIDX: Repeat Germline Testing L38429 - MoIDX: Repeat Germline Testing	A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A55295 - Billing and Coding: MoIDX: Myriad's BRCAnalysis CDx A55224 - Billing and Coding: MoIDX: Myriad's BRCAnalysis CDx A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes A55602 - Billing and Coding: MoIDX: <i>PIK3CA</i> A55200 - Billing and Coding: MoIDX: <i>PIK3CA</i>
Ovarian	<i>BRIP1</i>	No results	No results
	<i>RAD51C</i>	No results	No results
	<i>RAD51D</i>	No results	No results
Additional Searches		L36163 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing L36813 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing L38353 - MoIDX: Repeat Germline Testing L38429 - MoIDX: Repeat Germline Testing	A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A55295 - Billing and Coding: MoIDX: Myriad's BRCAnalysis CDx A55224 - Billing and Coding: MoIDX: Myriad's BRCAnalysis CDx A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes
Li Fraumeni		L36163 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing L36813 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing L38125 - MoIDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies L38176 - MoIDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	A55221 - Billing and Coding: MoIDX: <i>TP53</i> Gene Test A55487 - Billing and Coding: MoIDX: <i>TP53</i> Gene Tests (N) A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes

Additional Searches		L36813 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing (Wise)	A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57332 - Billing and Coding: MoIDX: Repeat Germline Testing (N) A55221 - Billing and Coding: MoIDX: <i>TP53</i> Gene Test A55487 - Billing and Coding: MoIDX: <i>TP53</i> Gene Tests (N)
Breast and Gastric	<i>CDH1</i>	No results	A55971 - Billing and Coding: <i>CDH1</i> Genetic Testing A55622 - Billing and Coding: <i>CDH1</i> Genetic Testing A57353 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A56901 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes
Additional Searches		No results	A55622 - Billing and Coding: <i>CDH1</i> Genetic Testing
Colon (Lynch)	<i>MLH1</i>	L36374 - MoIDX: Genetic Testing for Lynch Syndrome L36793 - MoIDX: Genetic Testing for Lynch Syndrome	A57353 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A56901 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes
	<i>MSH2</i>	L36374 - MoIDX: Genetic Testing for Lynch Syndrome L36793 - MoIDX: Genetic Testing for Lynch Syndrome	A57353 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A56901 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes

	<i>MSH6</i>	<p>L36374 - MoIDX: Genetic Testing for Lynch Syndrome</p> <p>L36793 - MoIDX: Genetic Testing for Lynch Syndrome</p>	<p>A57353 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing</p> <p>A56901 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing</p> <p>A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing</p> <p>A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing</p> <p>A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome</p> <p>A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome</p> <p>A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)</p> <p>A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)</p> <p>A57332 - Billing and Coding: MoIDX: Repeat Germline Testing</p> <p>A57100 - Billing and Coding: MoIDX: Repeat Germline Testing</p> <p>A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes</p> <p>A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes</p>
	<i>PMS2</i>	<p>L36374 - MoIDX: Genetic Testing for Lynch Syndrome</p> <p>L36793 - MoIDX: Genetic Testing for Lynch Syndrome</p>	<p>A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing</p> <p>A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing</p> <p>A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome</p> <p>A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome</p> <p>A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)</p> <p>A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)</p> <p>A57332 - Billing and Coding: MoIDX: Repeat Germline Testing</p> <p>A57100 - Billing and Coding: MoIDX: Repeat Germline Testing</p> <p>A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes</p> <p>A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes</p>
	<i>EPCAM</i>	<p>L36374 - MoIDX: Genetic Testing for Lynch Syndrome</p> <p>L36793 - MoIDX: Genetic Testing for Lynch Syndrome</p>	<p>A57353 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing</p> <p>A56901 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing</p> <p>A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing</p> <p>A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing</p> <p>A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome</p> <p>A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome</p> <p>A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)</p> <p>A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)</p> <p>A57332 - Billing and Coding: MoIDX: Repeat Germline Testing</p> <p>A57100 - Billing and Coding: MoIDX: Repeat Germline Testing</p> <p>A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes</p> <p>A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes</p>

Additional Searches		<p>L36374 - MoIDX: Genetic Testing for Lynch Syndrome</p> <p>L36793 - MoIDX: Genetic Testing for Lynch Syndrome</p> <p>L36797 - MoIDX: <i>NRAS</i> Genetic Testing</p> <p>L36339 - MoIDX: <i>NRAS</i> Genetic Testing</p> <p>L38353 - MoIDX: Repeat Germline Testing</p> <p>L38429 - MoIDX: Repeat Germline Testing</p> <p>L36163 - MoIDX: <i>BRCA1</i> and <i>BRC A2</i> Genetic Testing</p> <p>L36813 - MoIDX: <i>BRCA1</i> and <i>BRC A2</i> Genetic Testing</p>	<p>A57353 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing</p> <p>A56901 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing</p> <p>A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRC A2</i> Genetic Testing</p> <p>A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRC A2</i> Genetic Testing</p> <p>A54420 - Billing and Coding: MoIDX: FDA-Approved <i>BRAF</i> Tests</p> <p>A55161 - Billing and Coding: MoIDX: FDA-Approved <i>BRAF</i> Tests</p> <p>A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome</p> <p>A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome</p> <p>A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)</p> <p>A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)</p> <p>A57487 - Billing and Coding: MoIDX: <i>NRAS</i> Genetic Testing</p> <p>A57581 - Billing and Coding: MoIDX: <i>NRAS</i> Genetic Testing</p> <p>A57332 - Billing and Coding: MoIDX: Repeat Germline Testing</p> <p>A57100 - Billing and Coding: MoIDX: Repeat Germline Testing</p> <p>A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes</p> <p>A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes</p>
Breast and Uterine	<i>PTEN</i>	<p>L36163 - MoIDX: <i>BRCA1</i> and <i>BRC A2</i> Genetic Testing</p> <p>L36813 - MoIDX: <i>BRCA1</i> and <i>BRC A2</i> Genetic Testing</p> <p>L36797 - MoIDX: <i>NRAS</i> Genetic Testing</p> <p>L36339 - MoIDX: <i>NRAS</i> Genetic Testing</p>	<p>A57353 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing</p> <p>A56901 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing</p> <p>A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRC A2</i> Genetic Testing</p> <p>A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRC A2</i> Genetic Testing</p> <p>A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome</p> <p>A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome</p> <p>A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)</p> <p>A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)</p> <p>A57332 - Billing and Coding: MoIDX: Repeat Germline Testing</p> <p>A57100 - Billing and Coding: MoIDX: Repeat Germline Testing</p> <p>A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes</p> <p>A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes</p>
Additional Searches		No results	No results
Breast and Colon	<i>CHEK2</i>	<p>L36163 - MoIDX: <i>BRCA1</i> and <i>BRC A2</i> Genetic Testing</p> <p>L36813 - MoIDX: <i>BRCA1</i> and <i>BRC A2</i> Genetic Testing</p>	<p>A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRC A2</i> Genetic Testing</p> <p>A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRC A2</i> Genetic Testing</p> <p>A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome</p> <p>A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome</p> <p>A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)</p> <p>A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)</p>
Breast	<i>BARD1</i>	No results	No results
Breast	<i>NF1</i>	No results	No results

Colon	APC	L36884 - MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing L37224 - MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing	A57353 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A56901 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes
Colon (Juvenile Polypsis Syndrome)	<i>BMPRIA</i>	No results	A57353 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A56901 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes
	<i>SMAD4</i>	No results	A57353 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A56901 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes
Additional Searches		No results	No results
Colon (Adenomatous Polypsis)	<i>GREM1</i>	No results	A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)
	<i>POLD1</i>	No results	No results
	<i>POLE</i>	No results	No results
Additional Searches		No results	No results

Colon (MUTYH-Associated Polyposis)	<i>MUTYH</i>	L36884 - MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing L37224 - MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing L36374 - MoIDX: Genetic Testing for Lynch Syndrome L36793 - MoIDX: Genetic Testing for Lynch Syndrome	A57353 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A56901 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes
Additional Searches		No results	No results
Colon (Peutz-Jeghers Syndrome)	<i>STK11</i>	No results	A57353 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A56901 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57332 - Billing and Coding: MoIDX: Repeat Germline Testing A57100 - Billing and Coding: MoIDX: Repeat Germline Testing A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes
Additional Searches		No results	No results
Pancreatic	<i>CDKN2A</i>	No results	A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing (N) A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes
Additional Searches		L36163 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing L36813 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing L36374 - MoIDX: Genetic Testing for Lynch Syndrome L36793 - MoIDX: Genetic Testing for Lynch Syndrome	A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A55295 - Billing and Coding: MoIDX: Myriad's BRCAnalysis CDx A55224 - Billing and Coding: MoIDX: Myriad's BRCAnalysis CDx A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes
Malignant Pleural Mesothelioma	<i>BAP1</i>	No results	No results
Additional Searches		No results	No results

Melanoma	<i>CDK4</i>	L36797 - MoIDX: <i>NRAS</i> Genetic Testing L36339 - MoIDX: <i>NRAS</i> Genetic Testing	No results
	<i>MITF</i>	No results	No results
Additional Searches		L37210 - MoIDX: Decision Dx-UM (Uveal Melanoma) L37072 - MoIDX: Decision Dx-UM (Uveal Melanoma) L37748 - MoIDX: Melanoma Risk Stratification Molecular Testing L38018 - MoIDX: Melanoma Risk Stratification Molecular Testing L36163 - MoIDX: <i>BRC A1</i> and <i>BRC A2</i> Genetic Testing L36813 - MoIDX: <i>BRC A1</i> and <i>BRC A2</i> Genetic Testing L36797 - MoIDX: <i>NRAS</i> Genetic Testing L36339 - MoIDX: <i>NRAS</i> Genetic Testing	A57566 - Billing and Coding: MoIDX: Decision Dx-UM (Uveal Melanoma) A57622 - Billing and Coding: MoIDX: Decision Dx-UM (Uveal Melanoma) A57418 - Billing and Coding: MoIDX: DecisionDx-Melanoma (N) A57290 - Billing and Coding: MoIDX: Melanoma Risk Stratification Molecular Testing A56636 - Billing and Coding: MoIDX: Melanoma Risk Stratification Molecular Testing A54420 - Billing and Coding: MoIDX: FDA-Approved <i>BRAF</i> Tests A55161 - Billing and Coding: MoIDX: FDA-Approved <i>BRAF</i> Tests A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT) A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes

## Appendix 5: Unique Medicare Database Search Results and Frequencies

LCDs	Count	LCAs	Count	NCA's	Count
L36163 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing	10	A54996 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome	24	90.2 - Next Generation Sequencing (NGS)	2
L36339 - MoIDX: <i>NRAS</i> Genetic Testing	4	A55135 - Billing and Coding: MoIDX: Genetic Testing for Lynch Syndrome	24		
L36374 - MoIDX: Genetic Testing for Lynch Syndrome	8	A54420 - Billing and Coding: MoIDX: FDA-Approved <i>BRAF</i> Tests	2		
L36793 - MoIDX: Genetic Testing for Lynch Syndrome	8	A55161 - Billing and Coding: MoIDX: FDA-Approved <i>BRAF</i> Tests	2		
L36797 - MoIDX: <i>NRAS</i> Genetic Testing	4	A55200 - Billing and Coding: MoIDX: <i>PIK3CA</i>	1		
L36813 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing	11	A55602 - Billing and Coding: MoIDX: <i>PIK3CA</i>	1		
L36884 - MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing	2	A55221 - Billing and Coding: MoIDX: <i>TP53</i> Gene Test	2		
L37072 - MoIDX: Decision Dx-UM (Uveal Melanoma)	1	A55487 - Billing and Coding: MoIDX: <i>TP53</i> Gene Tests	2		
L37210 - MoIDX: Decision Dx-UM (Uveal Melanoma)	1	A55224 - Billing and Coding: MoIDX: Myriad's BRCAnalysis CDx	5		
L37224 - MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing	2	A55295 - Billing and Coding: MoIDX: Myriad's BRCAnalysis CDx	5		
L37748 - MoIDX: Melanoma Risk Stratification Molecular Testing	1	A55622 - Billing and Coding: <i>CDHI</i> Genetic Testing	2		
L38018 - MoIDX: Melanoma Risk Stratification Molecular Testing	1	A55971 - Billing and Coding: <i>CDHI</i> Genetic Testing	1		
L38125 - MoIDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	1	A57880 - Billing and Coding: MoIDX: Testing of Multiple Genes	22		
L38176 - MoIDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	1	A58121 - Billing and Coding: MoIDX: Testing of Multiple Genes	22		
L38353 - MoIDX: Repeat Germline Testing	3	A56636 - Billing and Coding: MoIDX: Melanoma Risk Stratification Molecular Testing	1		
L38429 - MoIDX: Repeat Germline Testing	3	A57290 - Billing and Coding: MoIDX: Melanoma Risk Stratification Molecular Testing	1		
		A57332 - Billing and Coding: MoIDX: Repeat Germline Testing	20		
		A57100 - Billing and Coding: MoIDX: Repeat Germline Testing	19		
		A57353 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing	12		
		A56901 - Billing and Coding: MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing	12		
		A57772 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)	26		

A57527 - Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)	26
A57355 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing	20
A57771 - Billing and Coding: MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing	19
A57487 - Billing and Coding: MoIDX: <i>NRAS</i> Genetic Testing	1
A57581 - Billing and Coding: MoIDX: <i>NRAS</i> Genetic Testing	1
A57566 - Billing and Coding: MoIDX: Decision Dx-UM (Uveal Melanoma)	1
A57622 - Billing and Coding: MoIDX: Decision Dx-UM (Uveal Melanoma)	1
A57418 - Billing and Coding: MoIDX: DecisionDx-Melanoma	1

#### Appendix 6: Medicare Database Second-Round Coding Results

Document title	Summary
<b>L36163 &amp; L36813 - MoIDX: <i>BRCA1</i> and <i>BRCA2</i> Genetic Testing</b>	Patient must show signs and symptoms of cancer in order for cost of genetic testing to be covered
	Provider must take step by step approach in order for testing to be covered. First, providers must test for microsatellite instability and immunohistochemistry. They may then perform germline genetic testing of <i>BRAF</i> followed by <i>MLH1</i> .
<b>L36374 &amp; L36793 - MoIDX: Genetic Testing for Lynch Syndrome</b>	Patient must show signs and symptoms of cancer in order for cost of genetic testing to be covered.
<b>L36884 &amp; L37224 - MoIDX: <i>APC</i> and <i>MUTYH</i> Gene Testing</b>	Cost of genetic testing will be covered for anyone with history/suspicion of Familial Adenomatous Polyposis (FAP), Attenuated FAP (AFAP) or MYH-associated polyposis (MAP) with a personal history of $\geq 20$ adenomas over a lifetime.

<p><b>L37748 &amp; L38018 - MoIDX: Melanoma Risk Stratification Molecular Testing</b></p>	<p>Molecular diagnostic tests used to assist in risk stratification of melanoma patients are covered when both criteria are met:</p> <ol style="list-style-type: none"> <li>1. The patient has a personal history of melanoma AND: <ol style="list-style-type: none"> <li>a. Either: <ol style="list-style-type: none"> <li>i. Has Stage T1b and above OR</li> <li>ii. Has T1a with documented concern about adequacy of microstaging</li> </ol> </li> <li>b. Is undergoing workup or being evaluated for treatment, AND</li> <li>c. Does not have metastatic disease AND</li> <li>d. Presumed risk for a positive Sentinel Lymph Node Biopsy (SLNB) based on clinical, histological, or other information is &gt;5% AND</li> <li>e. Has a disease stage, grade, and Breslow thickness (or other qualifying conditions) within the intended use of the test</li> </ol> </li> <li>2. The TEST has demonstrated, as part of a Technical Assessment: <ol style="list-style-type: none"> <li>a. Clinical validity of analytes tested in predicting metastatic disease in peer-reviewed scientific literature</li> <li>b. Utility beyond clinical, histological, and radiographical factors in the ability to accurately stratify patients into risk groups to manage patient care</li> <li>c. Appropriate analytical validity</li> <li>d. Performance characteristics equivalent to other covered, similar tests</li> </ol> </li> </ol> <p>Genetic testing is considered "reasonable and necessary where it has both shown an ability to enhance risk stratification and where this risk stratification may be used to select among number of different consensus recommended management approaches."</p>
<p><b>L38125 &amp; L38176 - MoIDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies</b></p>	<p>Genetic testing may be covered before a patient is diagnosed with cancer, but they must have an undefined cytopenia for more than four months. Otherwise, patient must show signs and symptoms of cancer in order for cost of genetic testing to be covered</p>
<p><b>L38353 &amp; L38429 - MoIDX: Repeat Germline Testing</b></p>	<p>Repeat testing may be considered when there is established clinic utility presented in the remaining genes in the test.</p>

## Appendix 7: Medicare Database Required Documentation

Document title	Required documentation
<p><b>L36163 &amp; L36813 - MoIDX: BRCA1 and BRCA2 Genetic Testing</b></p>	<p>"The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Coverage Indications, Limitations, and/or Medical Necessity") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.</p> <p>Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available to the MAC upon request."</p>

<p><b>L36374 &amp; L36793 - MolDX: Genetic Testing for Lynch Syndrome</b></p>	<p>"This contractor expects the ordering/treating physician or pathologist to obtain sufficient clinical and family history to warrant first-line testing (IHC/MSI), and subsequent targeted MMR germ-line testing or for germ- line mutation exceptions (as above). The clinical/family data to support IHC/MSI testing should be documented in the test interpretation/report and the information should be available to the lab performing targeted testing to assist the lab in the appropriate selection of target genes. Labs performing MMR germ- line panels without appropriate selection of targeted genes based on patient data, screening test (MSI/IHC) results, or exceptions are not reasonable and necessary.</p> <p>This contractor recognized that there is some variation in the order of testing based on tissue availability, prevalence, patient history, test availability, testing turn-around time and patient treatment schedule. However, the contractor does not expect routine MMR germ-line mutation testing prior to appropriate screening (IHC/MSI)."</p>
<p><b>L36884 &amp; L37224 - MolDX: APC and MUTYH Gene Testing</b></p>	<p>None reported</p>
<p><b>L37748 &amp; L38018 - MolDX: Melanoma Risk Stratification Molecular Testing</b></p>	<p>None reported</p>
<p><b>L38125 &amp; L38176 - MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies</b></p>	<p>"Given the abundant literature on genetic and genomic testing in cancer diagnosis and care, this contractor feels strongly that NGS methodology for testing is appropriate for use in Medicare Beneficiaries. However, given the variability for what information tests can provide, additional information must be submitted by providers to ensure the contractor A) understands what test is being performed; B) Why it is being performed; C) If the test is both necessary and reasonable for cancer care for its intended use."</p>
<p><b>L38353 &amp; L38429 - MolDX: Repeat Germline Testing</b></p>	<p>None reported</p>