How-to-Guide

Unraveling Genetic Testing Benefits

Catalyst for Payment Reform designed this How-to-Guide to help educate and introduce employers and other health care purchasers to developments in genetic testing and the implications for their health care purchasing strategies.

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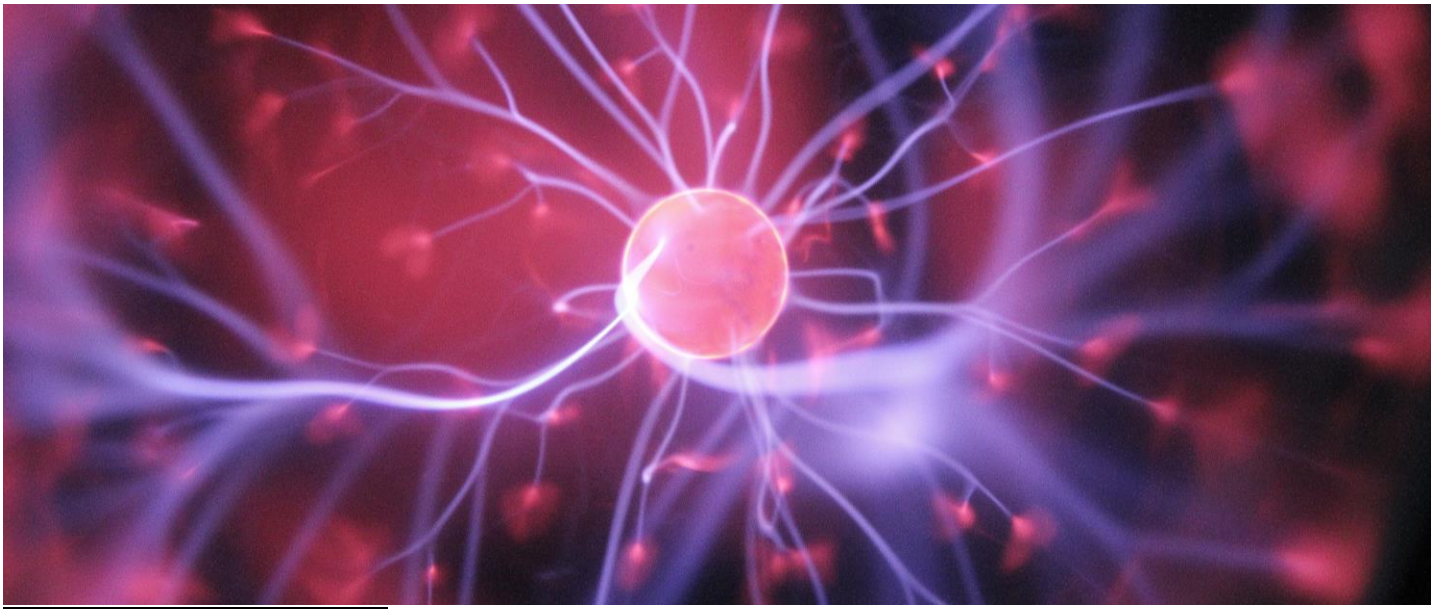
Table of Contents

Introduction: Genetic Testing

The end of the 20th century and the beginning of the 21st century has seen tremendous innovation in health care technology. Some of these advances have enabled the delivery of higher quality health care across all stages of care and have helped to increase life expectancy from 68.2 in 1950 to 78.6 years at the end of 2016.[1,2] Advanced imaging and scanning technologies have allowed providers more accurately to diagnose and assess the condition of their patients. Perhaps some of the greatest advances in medical science have come from learning more about human genetics. Genetic testing is a health care innovation that has resulted in quicker, more accurate diagnosis for specific conditions, and has made it possible for providers to identify the right treatment for specific patients and for patients to begin those treatments sooner. Since the completion of the Human Genome Project in 2003, the number of genetic tests available to patients has exploded; the latest research shows there are more than 75,000 genetic tests on the market and that number is increasing by ten each day.[3]

This exponential growth in the genetic testing field affects all stakeholders in the health care industry, including employers and other health care purchasers who pay for and provide health care coverage to employees. Purchasers are paying for an increasing number of these genetic tests through their health plan contracts and, as a result, are seeing higher costs. Payers have also taken notice of this growth and are investing in evaluation and management of genetic testing, both internally and by establishing partnerships with specialty vendors. Genetic testing specialty vendors are reaching out directly to employers and consumers selling products or services, such as genetic screening services and support. Aware of the potential of genetic testing to assist with diagnosis and identifying treatment options, but still uncertain of the value or necessity for certain tests, purchasers are investing time to get up to speed about the space.



[1] "Life expectancy at birth, at 65 years of age, and at 75 years of age, by race and sex: United States, selected years 1900–2007." Centers for Disease Control and Prevention. National Center for Health Statistics. 2010. https://www.cdc.gov/nchs/data/hus/2010/022.pdf.
[2] "Mortality in the United States, 2016." Centers for Disease Control and Prevention. National Center for Health Statistics. December 2017. https://www.cdc.gov/nchs/data/databriefs/db293.pdf.
[3] "Genetic Test Availability and Spending: Where Are We Now? Where Are We Going?" Health Affairs. May 2018. https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1427.

About the How-to-Guide on Genetic Testing

Catalyst for Payment Reform (CPR) designed this How-to-Guide on Genetic Testing to help educate and introduce employers and other health care purchasers about recent developments in the genetic testing space and the implications for their health care purchasing strategies. It includes:

- Definitions, terminology, and key concepts underlying genetic testing
- An overview of the scope of genetic testing
- A discussion of the benefits and challenges of genetic tests
- A look at the stakeholders in the space
- How employers can address genetic testing coverage for their populations
- What is on the horizon as the field continues to evolve

CPR thanks Jeffrey M. Davis, MD, MPH, Senior Health Management Consultant at Willis Towers Watson, for his input in developing this How-to-Guide. Dr. Davis served as a subject matter expert during CPR's employer collaborative, "Navigating the Potential Benefits and Unintended Consequences of Genetic Testing", which was formed to educate employers on the risks and opportunities in the field of genetic testing. CPR collaboratives are small groups of employers and other health care purchasers that work together to tackle a specific health care purchasing challenge or learn about a specific topic over a defined time period. Purchasers can learn more about this collaborative and others at catalyze.org.

Definitions, Terminology, and Key Concepts

Before diving deeper into genetic testing and its impact on purchasers and consumers, it's important to cover some definitions, terminology, and concepts underlying human biology and genetic testing.

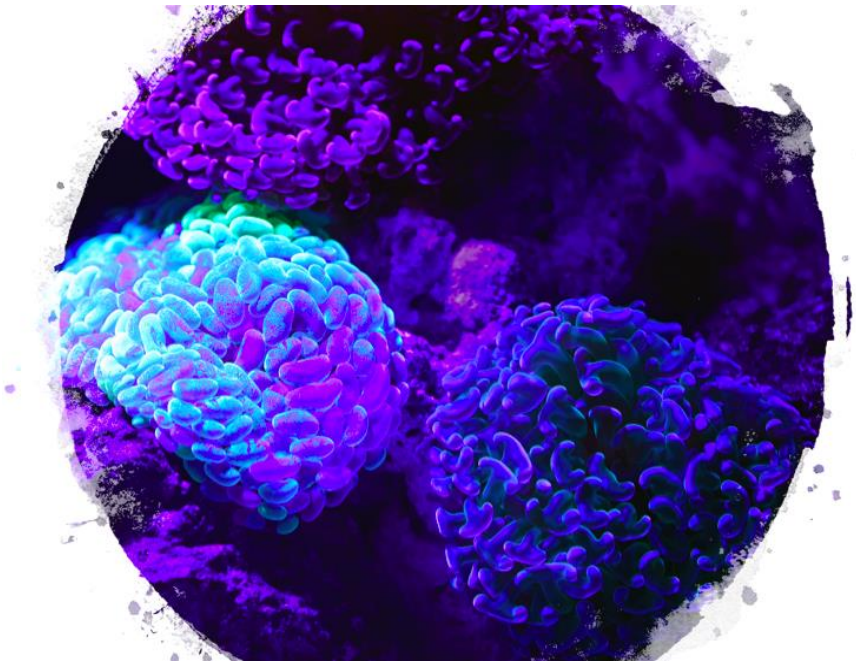
What are genes?

The human body is made up of trillions of cells – scientists estimate there are up to 40 trillion of them in each one of us![4] These cells, such as red blood cells, are made up of several components, notably a cytoskeleton (which gives the cell structure), cytoplasm (the fluid that surrounds the nucleus), mitochondria (which create energy for the cell and contain their own separate genetic material) and, most notably, the nucleus.[5] The nucleus, the "command center" of the cell, contains deoxyribonucleic acid, commonly referred to as DNA, which is packaged into chromosomes.[6] Normally, each cell contains 23 pairs of chromosomes, or 46 chromosomes in total, and each chromosome contains many genes.[7] Genes are units of DNA transferred from

[4] "How many cells are in the human body?" Medical News Today. July 12, 2017. https://www.medicalnewstoday.com/articles/318342.php.
[5] "What is a cell?" National Institutes of Health. U.S. National Library of Medicine. Genetics Home Reference. October 23, 2018. https://ghr.nlm.nih.gov/primer/basics/cell.
[6] "What is a cell?" National Institutes of Health. U.S. National Library of Medicine. Genetics Home Reference. October 23, 2018. https://ghr.nlm.nih.gov/primer/basics/cell.
[7] "How many chromosomes do people have?" National Institutes of Health. U.S. National Library of Medicine. Genetics Home Reference. October 23, 2018. https://ghr.nlm.nih.gov/primer/basics/howmanychromosomes.

parent to offspring that determine a certain characteristic or trait in an individual. The Human Genome Project estimates that humans have 20,000-25,000 genes.[8]

Discovering DNA and Linking it to Disease



While the cell was first discovered in the mid-1600s, it wasn't until over 200 years later that DNA was discovered in a human white blood cell. Nearly 80 years after that, in 1944, DNA was identified as the "transforming principle" of cells. Then in 1959, an additional copy of chromosome 21 was linked to Down Syndrome; however, it wasn't until 1983 that Huntington's Disease became the first mapped genetic disease. In 1994, the first gene to be associated with increased susceptibility to familial breast and ovarian cancer was identified. Located on chromosome 17, scientists named the gene BRCA1. In 1990, scientists embarked on an ambitious undertaking, the Human Genome Project. The goal was to sequence the entire human genome.[9] While genetic tests were developed prior to the mapping of the human genome, completion of this project in 2003 has resulted in an explosion of genetic tests available today for diseases such as breast cancer, Down syndrome, cystic fibrosis, Huntington's disease, muscular dystrophy, sickle cell anemia, hemophilia and many more.

Genetics versus Genomics

In this space, it's common to hear terms "*genetics*" and "*genomics*" used, often interchangeably. However, genetics and genomics are not the same, and it is important to clarify the difference. The World Health Organization defines genetics as the study of heredity, i.e., how traits and conditions are passed through an organism's genes from one generation to the next, from parent to offspring. On the other hand, genomics is the study of the entirety of an organism's genes called the genome, and how these genes collectively influence the growth and development of the organism. In short, genetics is the analysis of a single gene, while genomics evaluates all genes and their inter-relationships.[10] Throughout this How-to-Guide, there are references to both genetic testing and genomics.

[8] "What is a gene?" National Institutes of Health. U.S. National Library of Medicine. Genetics Home Reference. October 23, 2018. https://ghr.nlm.nih.gov/primer/basics/gene.
[9] "The History of DNA Timeline." DNA Worldwide. 2014. https://www.dna-worldwide.com/resource/160/history-dna-timeline#26.
[10] "WHO definitions of genetics and genomics." World Health Organization. http://www.who.int/genomics/geneticsVSgenomics/en/.

The Scope of Genetic Testing

For the purpose of this How-To Guide, it may be helpful for employers and other health care purchasers to think about and familiarize themselves with genetic testing in three distinct categories – 1) genetic diagnostic testing, 2) genetic screening, and 3) pharmacogenetics.

Genetic Diagnostic Testing

The key word in this category is "diagnostic." Genetic diagnostic testing is the use of a set of molecular diagnostic tests to confirm the presence or absence of a specific genetic mutation that enables a clinical diagnosis of a genetic-based condition in an individual.

For example, *cystic fibrosis* (CF), a disease characterized by a buildup of thick mucus, persistent lung infections, and other organ complications, is caused by a mutation in the genes that produce the cystic fibrosis transmembrane conductance regulator (CFTR) protein. Every person has two copies of the CFTR gene. A diagnosis of cystic fibrosis results when an individual inherits two copies of the mutated CFTR gene (one from each parent).[11]

Another example is *Down syndrome*, a condition that varies in severity and causes intellectual disability and developmental delays. Down syndrome results when an individual has an extra full or partial copy of chromosome 21. This mutation is caused by abnormal cell division early in the development of a fetus. Down syndrome is typically not hereditary.[12]

Lastly, *Huntington disease* is a rare, inherited condition causing progressive deterioration of neurons in the brain that usually develops in individuals between ages 35-44. It is caused by mutations in the HTT gene, a gene that provides instructions for making a protein called huntingtin and which is located on a numbered chromosome (chromosome 1-22). Unlike CF, Huntington disease requires only a single copy of the mutated gene to cause the disease in an individual.[13]

Genetic Screening

Genetic screening measures a person's *risk* of developing a condition based on the detection of a specific gene or selected genetic markers.

Carrier screening tests tell an individual whether he or she carries the gene for a specific genetic disorder. It is common for couples planning to have children to each take a carrier screening test to determine the likelihood of passing on a genetic condition to their offspring. Using the cystic fibrosis example above, if each parent has one copy of the CFTR gene mutation, there is a 50%

[11] "CF Genetics: The Basics." Cystic Fibrosis Foundation. https://www.cff.org/What-is-CF/Genetics/CF-Genetics-The-Basics/.
[12] "Down Syndrome." May Clinic. March 8, 2018. https://www.mayoclinic.org/diseases-conditions/down-syndrome/symptoms-causes/syc-20355977.
[13] "Huntington disease." National Institutes of Health. Genetic and Rare Diseases Information Center. July 8, 2015. https://rarediseases.info.nih.gov/diseases/6677/huntington-disease.

chance that their baby will have cystic fibrosis. Carrier screening tests identify other gene mutations associated with certain conditions, including Sickle cell disease, Tay-Sachs disease, and many others.[14]

Preimplantation screening tests detect the presence of genetic disorders in an embryo produced through in vitro fertilization (IVF) and can help potential parents make an informed decision on next steps in the IVF process. Preimplantation screening tests are beneficial when one or both parents has a family history of genetic disorders or is a known carrier of a genetic disorder or chromosomal abnormality, or when the mother is of advanced material age or has had prior miscarriages. Preimplantation screening tests supplement prenatal screening tests.[15]

Prenatal screening tests are performed on an expectant mother primarily during the first or second trimester of pregnancy and determine the likelihood the baby will have specific genetic birth defects. For example, the risk of having Down syndrome can be measured via a blood test and ultrasound between the 11th and 20th week of pregnancy. If the screening results show a positive result or high risk for the condition, then further genetic diagnostic testing can confirm the presence or absence of Down syndrome.[16]

Newborn screening tests are performed once a baby is born to detect if the baby has any of a number of serious and harmful conditions. The first newborn screening test was for Phenylketonuria, a metabolic disorder in which babies do not have the enzyme to process phenylalanine, a specific protein that is commonly found in our diet. Today, newborns are screened for additional conditions, including cystic fibrosis, sickle cell disease, and Tay-Sachs. Newborn screening is a service provided by each state's public health department and each state dictates which tests must be included.[17] An easy-to-use reference for the required screenings by state can be found at https://www.babysfirsttest.org/newborn-screening/states.

Hereditary cancer screening tests measure the risk of an individual developing a specific cancer based on gene mutations. BRCA1 and BRCA2 are perhaps the most well-known genes screened to identify an increased risk of cancer. These genes produce proteins that suppress tumors. Research shows that the presence of mutations in BRCA1 and BRCA2 are associated with a

[14] "Carrier Screening." The American College of Obstetricians and Gynecologists. Women's Health Care Physicians. April 2017. https://www.acog.org/Patients/FAQs/Carrier-Screening#screening.
[15] "Penn Preimplantation Genetic Testing Program." Penn Medicine. 2018. https://www.pennmedicine.org/for-patients-and-visitors/find-a-program-or-service/penn-fertility-care/embryo-screening.
[16] "Down Syndrome: Trisomy 21." American Pregnancy Association. July 2015. http://americanpregnancy.org/birth-defects/down-syndrome/.
[17] "About Newborn Screening: Newborn Screening 101." Baby's First Test. October 12, 2018. https://www.babysfirsttest.org/newborn-screening/screening-101.

significantly increased risk for females of breast and ovarian cancer and an increased risk for males of certain cancers as well.[18]

Pharmacogenetics

Pharmacogenetics is the third category of genetic testing. It is based on the concept that by testing certain genes for variants, providers may be more informed about which medications will work better for individual patients. This information could inform the physician about the appropriate dosage for the prescribed medication and/or which medications may present unwanted side effects for a specific patient. Some of the more evidence-based medications where such testing is being done clinically includes warfarin (used as a blood thinner to prevent blood clots), codeine (used for pain relief), and Abacavir (used to treat HIV). Furthermore, in October 2018, the U.S. Food and Drug Administration (FDA) permitted the first direct-to-consumer (DTC) pharmacogenetic test to be marketed, with some exceptions. The 23andMe Personal Genome Service Pharmacogenetic Reports provide information about genetic variants that may be associated with a patient's ability to metabolize certain medications, and can help inform treatment discussions with a provider.[19] However, it should be noted that pharmacogenomics is a new and burgeoning field within genetic testing, and there is still much for researchers and clinicians to learn about specific genes and the body's response to different drugs.

Benefits of Genetic Testing

Provides early diagnosis or risk detection

Genetic screening tests can inform people if they are at increased risk for a condition and/or advise whether they should receive additional genetic diagnostic testing. Individuals who are aware that they are at a higher risk for a certain condition are more informed, can monitor their health more closely, and/or implement lifestyle changes to lessen the risk of acquiring the condition.

Reduces uncertainty

Diagnostic genetic tests have the potential to reduce uncertainty, as the confirmed presence or absence of the gene mutation can confirm the presence or absence of the disease or condition.

Can provide insight into the most effective treatment

When it comes to prescribing medications for certain conditions, genetic testing can identify those drugs that may be more effective at treatment (and at which dosage level) than others for an individual. However, it is important to note that genetic testing of a given medication only

[18] "BRCA Mutations: Cancer Risk and Genetic Testing." National Cancer Institute. January 30, 2018. https://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet#q1.
[19] "FDA authorizes first direct-to-consumer test for detecting genetic variants that may be associated with medication metabolism." U.S. Food & Drug Administration. October 31, 2018. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624753.htm.

indicates a population-based probability that the drug will work or cause a side effect – the testing is not predictive of results for an individual patient.

Is useful for informing other family members

If individuals receive test results showing a mutation for a specific gene that is known to be inherited, they then can disclose the results to other family members. These family members can then choose to have genetic testing to confirm the presence or absence of the same mutation that indicates disease or shows increased risk.

Could be viewed as a perk to employees

Employers that are looking for ways to recruit and retain top talent may consider offering a genetic testing benefit to their employees. Such a genetic testing benefit might provide low or no cost genetic screening to assess an employee's risk for developing different types of cancers. While including a benefit like this may not sway a recruit one way or another, including the benefit as part of a perks package may be viewed more favorably by the recruit.

The use of genetic testing to enhance employee wellness

There are several vendors in the marketplace who are claiming that genetic variants associated with obesity, appetite, a person's response to exercise and even compulsive behavior can be used to increase employee engagement in wellness. Their rationale is that by informing individuals about selected lifestyle risk factors through genetic testing of these variants, these individuals can modify their diet, exercise, and other habits to lead a healthier lifestyle that could result in a positive impact on the company's overall health care costs. Currently, however, there is no good evidence that learning the result of genetic tests leads to sustained behavior change.

Challenges of Genetic Testing

Sense of false certainty

While diagnostic genetic tests can eliminate uncertainty by confirming the presence or absence of a disease, the results from a genetic screening test may also result in a sense of false certainty. A screening test assesses an individual's *risk* of developing a disease, but cannot determine with any degree of certainty if, or when, the disease will manifest. Having a pathogenic or likely pathogenic genetic variant does not equate to a diagnosis, just like having a benign or likely benign genetic variant does not mean an individual will never contract a specific condition.

Can result in patient anxiety

Genetic testing can leave patients with little more than the knowledge – and consequent worry and stress - that they *might* develop a serious condition. Even though studies on this topic have

been mixed, there is still reasonable concern about the generation of personal and/or family anxiety if an individual is identified as higher risk and the condition is one for which there are no preventive measures that can be taken, and/or the condition does not have an existing cure.

Could result in additional testing

Whether a test is diagnostic or screening, it can result in additional testing. A genetic diagnostic test that is negative could leave more questions than answers, resulting in additional testing to confirm a diagnosis. A genetic screening test (e.g., prenatal screening test) that suggests a diagnosis could result in a provider ordering a genetic diagnostic test that may or may not confirm a diagnosis.

Patients could receive inaccurate test results

Although significant advances have been made in genetic testing, inaccurate test results and the harms associated with them are still possible. Research indicates that prenatal genetic tests and direct-to-consumer (DTC) genetic tests could report false-positives, or the presence of a disease or condition when none exists.[20,21] False negatives, or results reporting no sign of disease when the individual actually has the condition, are less prevalent but do exist as well.[22] Patients who receive false negatives may not take medical action to treat a disease and allow it to develop further, while patients who receive false positives can undergo unnecessary medical services and procedures that are also potentially harmful (both physically and economically).

Could disadvantage other types of insurance coverage

The Genetic Information Non-Discrimination Act (GINA), prohibits health insurance companies and employers from engaging in discrimination on the basis of genetic information for health insurance and employment. GINA is applicable only to health insurance and does not prevent disclosure of genetic information for other insurance types, e.g., life insurance, disability insurance or long-term care insurance. For instance, an individual can voluntarily offer genetic test results or family history information to their medical provider, the medical provider can make notes in the individual's medical record, and that information can then potentially be used to deny the individual access to these other types of insurance coverage as part of that insurer's medical underwriting process.[23]

[20] "First Trimester Screen." American Pregnancy Association. September 2, 2016. http://americanpregnancy.org/prenatal-testing/first-trimester-screen/.
[21] "False-positive results released by direct-to-consumer genetic tests highlight the importance of clinical confirmation testing for appropriate patient care." Genetics in Medicine. March 22, 2018. https://www.nature.com/articles/gim201838).
[22] "False Negative NIPT Results: Risk Figures for Chromosomes 13, 18 and 21 Based on Chorionic Villi Results in 5967 Cases and Literature Review." PLOS. January 15, 2016. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0146794.
[23] "Genetic Information Nondiscrimination Act Guidance (2009). HHS. Office for Human Research Protections. March 24, 2009. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html.

Genetic Testing Challenges Specific to Purchasers

Genetic testing is costly (and unlikely to lead to long-term savings)

While the cost of sequencing the human genome has dropped precipitously since the completion of The Human Genome Project, especially during the past ten years due to the use of "second generation DNA sequencing platforms,"[24] the cost of a genetic test ranges from $100 to more than $2,000. Many factors can impact the cost. These include whether more than one test is necessary, whether other family members need testing, interpretation of the results, and genetic counseling support. In addition, until a longitudinal independent study is done that demonstrates a return on investment for genetic testing, it is unlikely to lead to long-term savings. And on the contrary, conducting broad-based genetic screening on predominantly low-risk people is not only not cost-effective from a population perspective, but can result in false positive findings that increase the cost of care through additional testing, which bring the additional risk of potential complications.

Some employees are skeptical of their employer's motivation

Despite the protections in place regarding health insurance and employment, many individuals are rightfully concerned about their genetic information getting into the wrong hands or being used against them. They may question why their employer is offering this type of benefit and what the employer and vendor will do with their genetic information. Even if an employer thinks they are benefitting their population by covering genetic testing, the rollout of such an offering must address the potential concerns of the employee population. For example, employers can reiterate the protections of GINA, and that the offering is a voluntary benefit.

Multi-gene panel tests and clinical appropriateness

In the past five years, technological advancements in genetic testing have given providers the ability to test multiple genes simultaneously to look for mutations. A study by scientists at Stanford and other institutions published in the May 2018 issue of JAMA Oncology indicate these multi-panel tests for hereditary breast cancer "yield more clinically useful results and are rapidly becoming the norm."[25] However, multi-gene panel tests present yet another challenge for employers, other health care purchasers, and other health care stakeholders, such as payers and providers, in understanding genetic testing – what is the clinically appropriate panel to test? As of the date of this publication, the first page of Google search results for "hereditary cancer panel" shows panels testing anywhere from 25 to 146 genes. In many cases, a provider ordering a genetic test for her patient must rely on the laboratory's knowledge of the most clinically appropriate test. And a laboratory has a potential incentive to recommend a larger panel, as more tests result in more revenue. The advent of multi-panel tests has also resulted in the

[24] "DNA Sequencing Costs: Data." National Institutes of Health. National Human Genome Research Institute. April
[25] "Multigene testing replacing BRCA tests for breast cancer risk." Stanford Medicine News Center. May 10, 2018. https://med.stanford.edu/news/all-news/2018/05/multigene-testing-replacing-brca-tests-for-breast-cancer-risk.html.

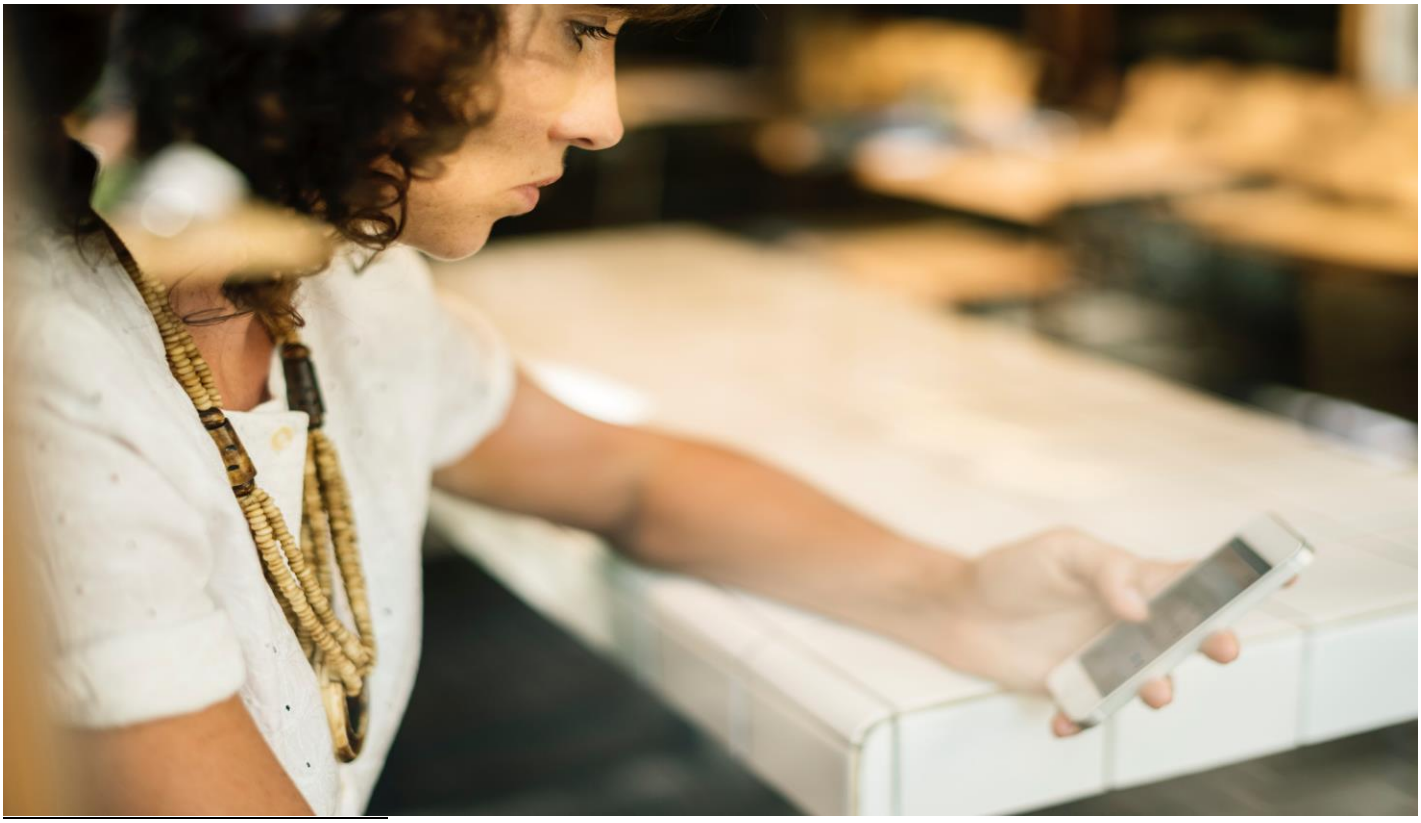
discovery of an increasing number of genetic variants of uncertain significance. As employers search for value from genetic testing, the questionable clinical utility may pose one of the greatest impediments.

Genetic counseling is critical support

Genetics is a complex scientific field, and patients with access to genetic testing also need access to genetic counselors who possess knowledge of genetics and genetic testing and are trained to discuss testing as well as test results with patients.

Pre-genetic test counseling can help individuals decide if testing is right for them, and if so, help them identify which tests are appropriate and what to expect during and after the process. Pre-test counseling is imperative in helping to ensure informed consent from the patient, i.e., the patient fully understands the relevant clinical information, the procedure he is consenting to, the process, the risks and benefits associated with it, and is ultimately able to grant permission for the test.[26] In addition, pre-test counseling provides the patient with the opportunity to share any personal or family history and ask any questions associated with the test. Any provider that offers genetic testing should also offer access to pre-test genetic counseling, whether the genetic counselors are within the provider organization or through an external partner.

Moreover, genetic counseling is not limited to pre-test counseling. Post-genetic test counseling is also essential for helping patients interpret results and identify next steps such as treatment options and other resources. Genetic counseling can mitigate the risk of results creating more uncertainty.



[26] "Informed Consent." American Medical Association. 2018. https://www.ama-assn.org/delivering-care/informed-consent.

Opportunities for Purchasers in Their Health Plan Relationship

Employers and other health care purchasers typically cover genetic testing today through their health plan or other third-party administrator relationships. Health plans have been monitoring this field for years and have developed extensive policies that rely on scientific research to make decisions about which tests to cover. Several of these payer-specific medical policies are listed below:

- **Aetna:** BRCA testing, genetic testing, genetic counseling, pharmacogenetic and pharmacodynamic testing
- **Anthem:** genetics
- **Cigna:** genetics, genetic testing and counseling program
- **UnitedHealthcare:** carrier testing for genetic diseases, genetic testing for hereditary cancer, pharmacogenetic testing

The health plans also have processes in place, or partner with other experts, to review regularly the emerging evidence related to new tests coming to market and make determinations on whether to cover them. Most employer-purchasers do not have the bandwidth to review and question these policies, nor do they have the interest in doing so. Instead, they tend to rely on the health plan's or genetic testing benefit manager's expertise.

However, the growing number of tests entering the market, particularly next generation sequencing platform tests, presents a challenge for health plans attempting systematically to evaluate tests for coverage. Because of the overwhelming number of new tests, payers do not typically evaluate these tests proactively when they enter the market. Rather, they review them on a reactive basis after the tests have been ordered by providers requesting pre-authorization, or for claim reimbursement if the test has already been performed. Because only about 200 Current Procedural Terminology (CPT) codes exist for the tens of thousands of genetic tests in the market, there is no clear billing method and health plans are thus faced with the challenge of identifying the test performed, and whether it's appropriate and valid.[27]

There are some tactics that purchasers can employ to understand and manage the cost and utilization of these benefits by their members.

1. Purchasers Can Ask Their Health Plan or Administrator Essential Questions

Purchasers that want to evaluate how effectively their health plan or administrator is monitoring this space can ask questions in four categories: medical policy/claims processing, benefit design, network design, and available resources. Within these categories, there is opportunity to obtain a summary or more detailed view into the health plan or administrator's processes.

[27] "Coverage and Reimbursement of Genetic Tests." National Human Genome Research Institute. February 14, 2018. https://www.genome.gov/19016729/coverage-and-reimbursement-of-genetic-tests/.

Medical policy/claims processing – Know about your health plan's guidelines:

SUMMARY
1. How does the health plan define "genetic testing"?
2. What is the health plan's medical policy for genetic testing coverage? Is there specific language on age, family history, personal medical history, etc.?
3. How frequently is the medical policy reviewed and updated?
4. How does the health plan stay up-to-date on the latest evidence in this rapidly evolving area?
DETAILED
5. How does the health plan categorize genetic tests that are not related to gene sequencing, but are tests related to the condition itself (e.g., testing pathways in a tumor)?
6. Explain any potential "gray area" in the medical policy for coverage. Is there opportunity for purchasers to customize coverage (e.g., require genetic counseling and/or medical necessity reviews for tests to be covered)?
7. Do medical policy review and updates occur more frequently than in other clinical areas?
8. How does the health plan handle payment for new genetic tests? What happens if a newer genetic test is submitted for claims payment, but the health plan hasn't developed a medical policy on that test yet?
9. How are genetic/molecular tests coded? What kind of codes are submitted? If there isn't a recognized code in the claims system, is the test automatically kicked out for manual review?
10. Are there specific types of genetic tests that are always kicked out for manual review? If not, do genetic testing claims get processed without any review?

Benefit Design – Know how tests are currently covered and understand strategies to manage utilization:

SUMMARY
1. Are there any genetic tests that are covered under preventive care? If so, which ones? What makes these tests high-value?
2. How are genetic tests covered under the health plan? Is the patient's cost sharing responsibility the lab copay/coinsurance? Explain circumstances where coverage may fall under another benefit provision.
3. Does the health plan offer a pre-certification program? If so, is it a core or buy-up offering?
DETAILED
4. If no genetic tests are covered as preventive care, does that mean that all genetic tests are diagnostic and reimbursed on a per test basis?
5. Are there high-value tests purchasers should cover as preventive care, and what makes the tests high-value?
6. How are multi-gene panel tests covered? Is this different than single-gene testing coverage? Why?
7. Does the professional fee cover both the interpretation and reporting of the result or is each a separate fee?
8. What are the review thresholds for a genetic test, e.g., cost, clinical utility, other?
9. Is pre- and post-testing genetic counseling covered? If so, at what level? Is it bundled in with the test, interpretation, and report?

10. Does the health plan require that the member receive genetic counseling prior to paying the lab for performing the test?
11. Which tests (or threshold) are subject to the pre-certification program? Is the threshold customizable by the purchaser?

Network Design – Know the plan's standards for in-network labs and other providers:

SUMMARY
1. Does the health plan identify physicians (e.g., on the provider search tool) that are board certified in medical genetics or are medical geneticists?
2. Does the health plan identify genetic counselors (e.g., on the provider search tool)? Does the health plan require board certification (e.g., American Board of Genetic Counselors)?
3. What are the health plan's standards for approving a lab for genetic testing?
4. How does the health plan monitor and evaluate labs on an ongoing basis?
DETAILED
5. Which types of providers most frequently order genetic tests?
6. Does the health plan contract with national labs for genetic testing?
7. Does the health plan contract with regional labs? How many regional labs are in the network? Does the health plan contract with these labs because specific providers want the lab in the network or do these labs offer unique capabilities?
8. How does the health plan address high-cost labs and/or labs that routinely order multi-panel testing? Does the health plan remove them from the network?
9. Are the health plan's contracting requirements different for labs that offer specialty testing, e.g., molecular testing? How large is the network for specialty testing?
10. Can an employer customize its network so that a narrower set of labs conducts genetic tests? If so, explain the process.

Resources – Know the plan's resources (and partners) that are available to providers and to consumers:

SUMMARY
1. Does the health plan cover access to pre- and post-genetic testing counselors?
2. Does the health plan work with an external partner to educate members and providers? If so, what services does the partner provide?
DETAILED
3. Are the genetic counselors (a) part of the health plan's clinical team, (b) part of the health plan's pre-certification program, or (c) available through an external partner? How does the health plan make members aware of this resource? Is access to counseling triggered when a provider orders a test?
4. How does the health plan educate network providers on which panels are clinically appropriate according to the research (and existing medical policy)?
5. Does the health plan educate providers on how to discuss genetic testing options and benefits with patients?

In August 2018, CPR hosted a series of educational webinars to wrap up its employer collaborative on genetic testing, inviting Aetna and UHC (as requested by the collaborative participants) to present to the purchaser audience attending the series. Aetna and UHC were

asked to follow the format of the questions above for their respective session. Purchasers can learn more about the series, watch the introductory session recording, and order the other recordings at catalyze.org.

2. *Purchasers Should Analyze Their Data*

During CPR's collaborative on genetic testing, CPR learned of one employer participant's experience requesting three years of claims data for genetic tests from their health plan, only to discover that the tests doubled between 2014 and 2016, and the associated cost went up nearly 250% during the three-year period. Digging deeper into their data, this employer discovered that while the cost and utilization increased across all categories of testing (e.g., BRCA, pharmacogenomics, prenatal) the cost more than quadrupled in an "unspecified" category. It was this bucket that the purchaser felt was a "black box," prompting them to inquire what the unspecified bucket represents and whether these tests were preauthorized. Using genetic testing claims data from their data warehouse, the employer was able to see what was in this unspecified category.

Based on this employer's experience, CPR developed a data request that purchasers can use to gather and analyze their data. With the data request, employers can ask for summary data (by genetic testing category) for the current and baseline year and/or detailed data (by test). The data request asks for cost and utilization data and automatically calculates trend.

Gen Testing_Plan Data Request_FINAL

This data request will help purchasers determine their costs from genetic testing, whether it is increasing, and examine utilization in their population. Such insights will enable them to implement strategies to help manage this area.

3. *Purchasers Can Implement Controls*

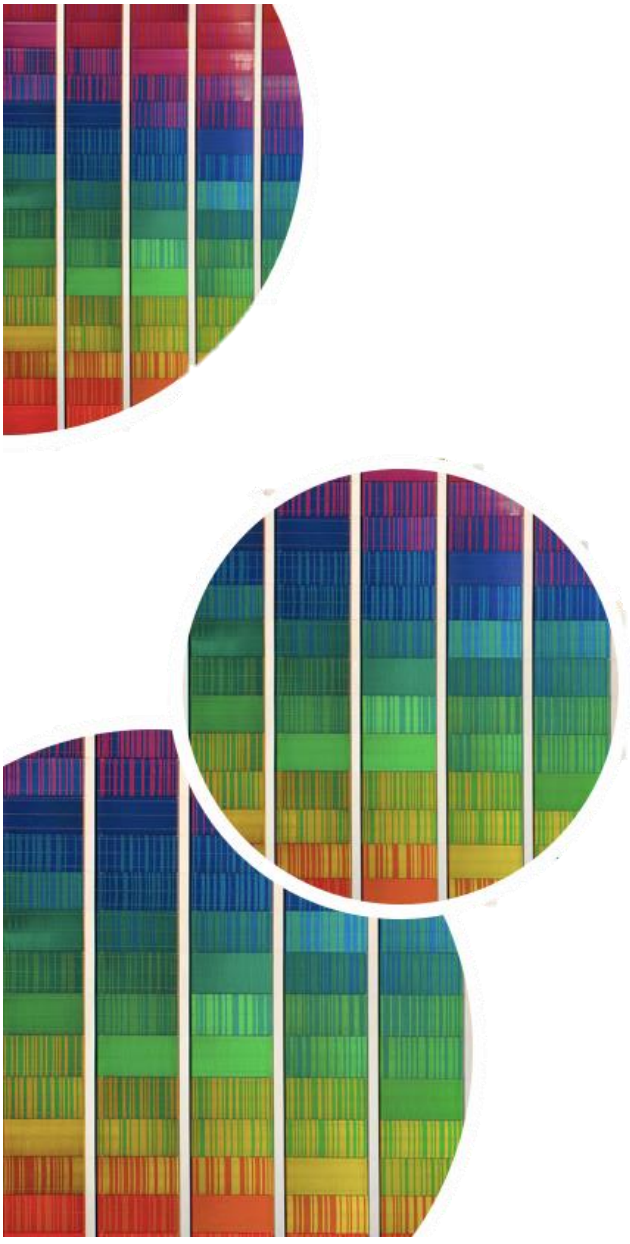
Continuing with the example above, the employer that discovered rapidly increasing genetic testing costs and utilization among its population determined that the "black box" was too unpredictable and implemented a precertification program with its health plan through its specialty vendor partner in 2018. This solution involves a review of requested tests to reduce unnecessary testing and ensure that panel tests are limited to clinically relevant genes. A precertification program also allows the health plan to educate the provider on the clinically appropriate test to order. The employer views it as a small investment to ensure that providers are doing the right thing.

Through the health plan, purchasers can understand which cost and health care utilization controls exist as a standard. Either through its health plan or a specialty vendor, purchasers can

explore opportunities to implement controls like the precertification program this employer implemented.

Playing a Supportive Role with Providers

Just as providers make determinations about what procedures their patients need, the same is true for ordering genetic tests. However, most providers are not experts on genetics or genetic testing. These knowledge gaps have implications for employers and other health care purchasers.



Ordering tests

With all the tests currently on the market and the influx of new tests daily, it can be overwhelming for providers who are on the frontlines with patients to know the appropriate genetic test to order. Further complicating matters is that regulatory authorities have not provided much assistance with determining appropriateness. The Food and Drug Administration (FDA) monitors and regulates DTC genetic testing services, such as those offered by 23andMe and Ancestry.com Inc., but it has not been as vigilant when it comes to laboratory-developed tests that are ordered by clinicians.

While DTC tests must seek FDA approval, tests ordered by physicians do not need approval.[28] The reasoning behind this is that providers will review test orders and determine which ones are appropriate, providing a level of consumer protection and professional oversight of testing; however, it is unclear whether providers know enough to serve this role.[29] A 2013 study found that while physicians felt confident ordering tests that look at a commonly known single gene (i.e. BRCA1 or BRCA2), they were less comfortable and less likely to order multi-gene panel tests due to concerns about the clinical usefulness of these tests, difficulty with interpreting results, lack of knowledge of genetics, and costs.[30] These findings still hold true today, as there are still doubts among providers as to the clinical utility of the inclusion of moderate-risk genes on

[28] "Genetic tests ordered by doctors race to market, while 'direct-to-consumer' tests hinge on FDA approval." STAT. March 16, 2018. https://www.statnews.com/2018/03/16/genetic-tests-fda-regulation/.
[29] "Genetic tests ordered by doctors race to market, while 'direct-to-consumer' tests hinge on FDA approval." STAT. March 16, 2018. https://www.statnews.com/2018/03/16/genetic-tests-fda-regulation/.
[30] "Survey: Physicians Need More Training About Cancer Gene Tests." City of Hope. June 12, 2013. https://www.cityofhope.org/blog/genetic-cancer-risk-screening.

some multi-gene panels.[31] Some skepticism on the part of providers might be healthy, but it may also mean that plans and employers may not be able to rely on providers to identify high-value testing services and distinguish them from low-value ones. Moreover, providers may have to defer to, or even rely on, the laboratories themselves to determine which test is needed. Many laboratories will provide consultation to providers on selecting a test, which can be problematic as laboratories have a potential incentive to recommend and perform testing on larger panels that are costlier.[32] One study estimated that 1 in 4 tests ordered were not medically indicated due to inappropriate test selection.[33]

Instead of providers evaluating and making determinations on the clinical validity of tests and multi-gene panels in real time,[34] other stakeholders can play a supporting role. For example, purchasers can establish precertification programs in which health plans, and other expert vendors, can advise a provider on whether a test is appropriate before the provider orders it. In addition, health plans and expert vendors can continue to educate and train providers so that they are more capable of determining appropriate testing on their own.

Interpreting results

As access to genetic testing becomes more widespread and is increasingly recognized as enabling the advancement of personalized medicine and adding value across all stages of care, there is growing demand for these services, but not necessarily equal growth in the knowledge needed to interpret test results. This is particularly true among providers who must respond directly to the questions of their patients. A 2018 study surveyed 488 primary care providers in New York City about their views on genetic testing for chronic diseases. While 74% believed genetic testing is clinically useful and 78% had received formal genetics education, only 14% felt confident about interpreting genetic test results.[35] Yet the survey also found that over the prior year, 36% of providers ordered a genetic test. This knowledge gap can lead to some of the risks and limitations outlined previously, such as increased uncertainty and patients not knowing next steps to take based on their test results. Another concern cited is the cascading effect of expensive, inappropriate, and potentially harmful medical treatment when a genetic risk is identified.[36] These challenges

[31] "Multigene Panel Testing and Breast Cancer Risk: Is It Time to Scale Down?" JAMA Oncology. September 2017. https://jamanetwork.com/journals/jamaoncology/article-abstract/2618070.
[32] "Genetic counselor review of genetic test orders in a reference laboratory reduces unnecessary testing." Am J Med Genet A. 2014 May;164A(5):1094-101. March 24, 2014. https://www.ncbi.nlm.nih.gov/pubmed/24665052.
[33] "Genetic counselor review of genetic test orders in a reference laboratory reduces unnecessary testing." Am J Med Genet A. 2014 May;164A(5):1094-101. March 24, 2014. https://www.ncbi.nlm.nih.gov/pubmed/24665052.
[34] "Multigene Panel Testing in Oncology Practice: How Should We Respond?", JAMA Network. JAMA Oncology. June 2015. https://jamanetwork.com/journals/jamaoncology/fullarticle/2174769.
[35] "Views of Primary Care Providers On Testing Patients For Genetic Risks For Common Chronic Diseases" Health Affairs. May 2018. https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1548.
[36] "What if your doctor offered genetic testing as a way to keep you healthy?." The Washington Post. May 28, 2018. https://www.washingtonpost.com/national/health-science/what-if-your-doctor-offered-genetic-testing-as-a-way-to-keep-you-healthy/2018/05/25/84b69238-5dd5-11e8-a4a4-c070ef53f315_story.html?noredirect=on&utm_term=.41a949194961.

highlight the need for patients to have access to genetic counseling and expert medical opinion services.

Monitoring and Managing Genetic Testing with Laboratories

With the influx of new genetic tests in the market, genetic testing laboratories are increasingly offering a greater variety of services. However, not all laboratories are created equal. Moreover, some of the tests these laboratories offer, such as multi-gene panels, may offer little or no additional value. This means purchasers need to give thought to the laboratories their members utilize.

Lab certification and test validity

Clinical laboratory testing is regulated by the Centers for Medicare & Medicaid Services (CMS) through the Clinical Laboratory Improvement Amendments (CLIA) program. In total, CLIA covers approximately 260,000 laboratories.[37] In addition to CLIA, the College of American Pathologists (CAP) offers an accreditation program which contains the requirements for different disciplines and laboratory types. CAP accreditation can also help laboratories meet CLIA requirements.[38]

CLIA certification and CAP accreditation offer a baseline; therefore, purchasers should understand whether their health plan requires these designations before accepting a laboratory provider into the network. The same goes for a specialty vendor, unless the vendor does not operate as a lab and instead sends the genetic test to a lab (preferably with these designations). Note that one shortcoming of CLIA certification for genetic testing is that CLIA reviews the analytical validity of a test but does not review its clinical validity.[39]

Analytical validity	Clinical validity
Does the test accurately predict the presence or absence of a gene or genetic variant?	Is the genetic variant being analyzed related to the presence, absence, or risk of a disease?

Interestingly, New York State requires information on the clinical validity of all tests performed on people living in the state. Purchasers can and should work with their health plan to evaluate whether they are paying for high-cost, multi-gene panel tests that include testing of some genes for no clinically valid reason. Health plans, or their partners, can either educate these laboratories when a test is not clinically valid or choose not to contract with the laboratory to conduct genetic testing.

CPR's detailed data request embedded above provides purchasers with the opportunity to request and analyze the two labs utilized most often for each test as well as the unit cost so that employers can begin to compare cost and lab orders for key labs.

Access to genetic counseling services

[37] "Clinical Laboratory Improvement Amendments (CLIA)." Centers for Medicare & Medicaid Services. September 19, 2018. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/Clia/.
[38] "Laboratory Accreditation Program." College of American Pathologists. 2018. https://www.cap.org/laboratory-improvement/accreditation/laboratory-accreditation-program.
[39] "Regulation of Genetic Tests." National Human Genome Research Institute. January 17, 2018. https://www.genome.gov/10002335/regulation-of-genetic-tests/.

Another potential sign of a high-quality genetic testing laboratory is one that offers access to genetic counseling. According to the National Society of Genetic Counselors, contacting genetic counselors in the laboratory is an option when considering the appropriateness of a genetics referral, ordering a genetic test for a patient, or getting assistance in interpreting genetic test results. Furthermore, it is not uncommon for laboratories to employ genetic counselors that serve as liaisons between providers and the laboratory.[40] In general, patient access to both pre- and post-genetic counseling is an important service. However, purchasers should understand the role of the genetic counselor for the labs their members use most frequently and whether they have any incentives to recommend multi-gene panel tests to the providers who seek their consultation.

Considering Specialty Vendors

While some employer-purchasers have contracted with vendors in this space, as described in the "Limitations and Precautions of Genetic Tests" section, many employer-purchasers are taking a wait-and-see approach to contracting with a genetic testing specialty vendor. Some have dipped their toe in by participating in a pilot program. Among the collaborative participants, CPR learned that all had met with a specialty vendor and one was in the midst of a pilot program with a specialty vendor that offered genetic testing for a specific department within the organization. Generally, the vendors that have forged some direct-to-purchaser relationships fall into a few different categories:

1. Specialty Vendors and Laboratories

The employer-purchaser and a specialty vendor can contract to provide employees and their eligible dependents access to a genetic testing kit. The employer may partially or fully cover the cost. Individuals send in their DNA sample for testing a specific set of genes linked to disease. They then receive a report and can also access a genetic counselor to discuss their results and the implications. Vendors in this space offer access to hereditary cancer testing (e.g., breast, colorectal, ovarian, and prostate cancer) and carrier or prenatal tests, among others. Employers should never receive patient-specific results of these tests.

2. Genetic Testing Benefit Managers

Recall the challenge one of CPR's collaborative participants faced – significantly increasing cost and utilization, much of it in an unspecified category in the administrator's reporting. The administrator subcontracted with a specialty vendor to provide genetic testing benefit management, i.e., prior authorization services to determine the appropriateness of a test ordered by a clinician and direct members to the most appropriate genetic testing laboratory to address their specific clinical situation. It is not yet commonplace for there to be "benefit managers" in this area as it is in radiology or physical therapy, but it may become more common with time.

[40] "Incorporating Genetic Counselors in Your Practice." National Society of Genetic Counselors. 2018. https://www.nsgc.org/page/incorporate-genetic-counseling.

3. Navigation and Education

The specialty vendor can serve as a genetic testing resource or expert, educating benefits staff and/or employees and their eligible dependents about whether testing is appropriate, which tests are appropriate, and the vendor may review results and next steps with individuals regarding their genetic test results. These vendors function as third-party genetic counselors and physicians without an attached laboratory.

4. Expert Medical Opinion Vendors

Expert medical opinion vendors (sometimes referred to as second opinion vendors) have increasingly contracted directly with employer-purchasers to offer their employees and eligible dependents access to a network of highly-rated providers for second opinions when they are diagnosed with a condition and are considering a treatment or procedure. While we did not dive deeply into expert medical opinion vendors as part of the scope of this collaborative, they certainly could play a role in helping to manage the appropriateness of specific genetic tests ordered by providers.

Framework to Evaluate Specialty Vendors

It can be daunting to meet with a vendor to discuss a topic that is relatively new, complex and rapidly developing. Like purchasers' approach to evaluating potential vendor partners in other areas of health care, they can evaluate a potential genetic testing partner by identifying a few priority areas and digging deeper. Below are some recommended areas to consider as purchasers evaluate potential partners. Note the evaluation requires both external information gathering as well as an intrinsic thought process on whether the potential solution is relevant and how members will utilize it. The framework below applies primarily to a vendor that offers or conducts genetic testing, however, purchasers can modify it to apply to other vendors in this space.

Category:	Evaluation Details:
1. Clinical Significance	• What is the evidence that these are the right gene(s) to test? • Is this the minimally necessary test to produce clinically significant findings? • What is the uncertainty associated with testing these gene(s)? • Is the test considered investigational and experimental?
2. Relevance	• Does the test address a key condition or risk in my population? • Does offering the test align with my organization's benefits philosophy or strategy? • Will offering the test fill an unmet need?

3. Test Effectiveness	• Before a test is ordered, are factors such as age, family history, etc. considered? • Will the test be sent to a certified lab (e.g., CAP, CLIA) for testing and interpretation? • What is the test's accuracy? • What makes the provider better than others at the testing and interpretation?
4. Member Engagement / Satisfaction	• Will the test increase member participation or completion of wellness and prevention activities? • Could the employees view the testing as an enhancement to the benefits program? • Is genetic counseling included on a pre-test/post-test basis? Is it from an independent or managed partner?
5. Investment	• What is the cost of the test, broken down by the actual laboratory testing and interpretation of the results? • What is the total anticipated upfront investment for this benefit? • How does the cost compare to other initiatives under consideration?
6. Cost Savings / Avoidance	• What hard or soft ROI is claimed, and how credible is it?

Developments for Purchasers to Watch

Everything covered up to this point in this How-To Guide includes background on the history of genetic testing, its benefits and challenges, and near-term actions that purchasers can take. However, diagnostics and genetic tests continue to advance. Here, we summarize a few developments that can advance genetic testing or act as disruptive technologies to this field.

1. Continued Decrease in the Cost of Whole Genome Sequencing

The cost of sequencing the human genome has come down substantially since the first one was sequenced in 2003, at a cost of $2.7 billion.[41] Today, the cost is under $1,000 and continues to decrease. One company promises to get the cost for whole genome sequencing down under $100 "probably in more than three years and fewer than ten." As the technology becomes better and we learn more about the human genome and specific genes, genetic testing ideally will provide greater certainty and direction for determining risk, diagnosis, and appropriate care. The decrease in cost of genomic sequencing will not necessarily result in lower costs to purchasers.

2. Further Integration of Genetic Testing into Routine Care

[41] "The Human Genome Project Completion: Frequently Asked Questions." National Human Genome Research Institute. October 30, 2010. https://www.genome.gov/11006943/human-genome-project-completion-frequently-asked-questions/.

In May 2018, Geisinger announced that the health system will start offering patients DNA sequencing as part of routine preventative care. The program began with a 1,000-patient pilot with plans to scale throughout the system of 3 million patients. President and CEO David Feinberg was quoted saying "We're going to start doing it the same way we would talk to patients about getting a cholesterol check…"[42] As genetic tests grow in popularity and their value, perceived or real, becomes more apparent, purchasers should be on the lookout for genetic testing to be integrated increasingly into routine and preventive care. Purchasers who consider this should implement a thoughtful evaluation program to assess clinical and financial outcomes.

3. Liquid Biopsy

Absent a cure for cancer, the ability to diagnose cancer in its earliest stage when it's more easily treatable is akin to the holy grail in medicine. Currently, multiple professional bodies provide cancer screening recommendations based on age, sex, family history, and other qualities. The U.S. Preventive Services Taskforce (USPSTF) has significant impact on purchasers, as any preventive services and screenings that it rates as an 'A' or 'B' are ones that the health plans (and their purchaser customers) must cover without consumer cost-sharing. However, some of the current best practice screening tests (i.e. colonoscopy for colorectal cancer or mammography for detecting breast cancer) are invasive and/or result in discomfort. Furthermore, when a possible mass is identified via these screening procedures a biopsy is subsequently performed which results in added costs and possible medical complications for the patient.

In contrast to a traditional biopsy, a liquid biopsy involves collecting a blood sample and testing it for cancer cells or for DNA from the tumor cells.[43] In January 2018, Johns Hopkins researchers published promising results from a study in which their liquid biopsy blood test was able to detect several types of cancer.[44] This area of diagnostics is promising, but will likely not be practical for a number of years.

4. Gene Editing

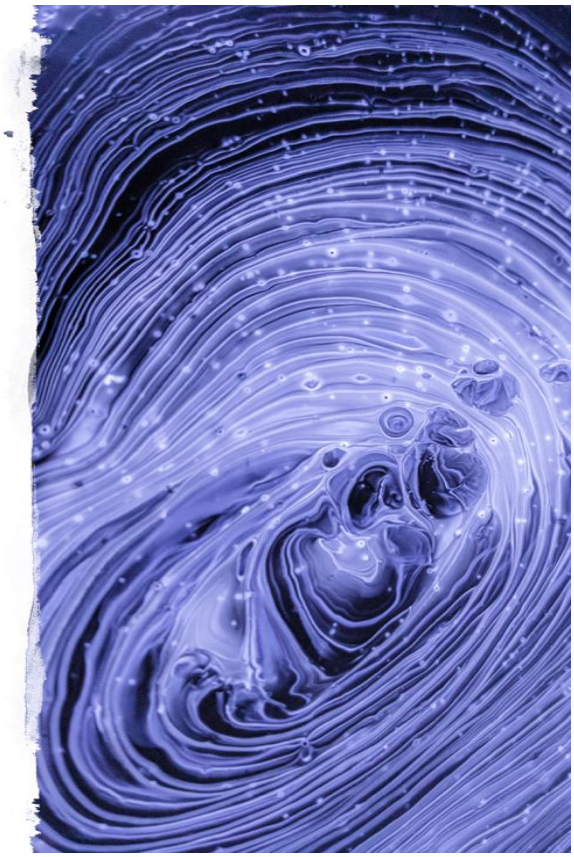
A recent development in the world of genomics is the ability to edit genes or change an organism's DNA. In late 2017, researchers infused gene editing tools into a patient's blood to treat an inherited disease called Hunters syndrome.[45] In February 2018, a second patient was added to the study.[46] In late 2018, a Chinese researcher announced that he had used CRISPR technology to alter genes of two newborns prior to implantation, sparking ethical concerns.[47]

[42] "Geisinger Says DNA Sequencing As Preventative Care Is Ready For The Clinic." Forbes. May 7, 2018. https://www.forbes.com/sites/elliekincaid/2018/05/07/geisinger-says-dna-sequencing-as-preventative-care-is-ready-for-the-clinic/#7335ca784d63.
[43] "NCI Dictionary of Cancer Terms." NIH. National Cancer Institute. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/liquid-biopsy.
[44] "Detection and localization of surgically resectable cancers with a multi-analyte blood test." American Association for the Advancement of Science. Science. January 18, 2018. http://science.sciencemag.org/content/early/2018/01/17/science.aar3247.
[45] "A human has been injected with gene-editing tools to cure his disabling disease. Here's what you need to know." American Association for the Advancement of Science. Science. November 15, 2017. https://www.sciencemag.org/news/2017/11/human-has-been-injected-gene-editing-tools-cure-his-disabling-disease-here-s-what-you.
[46] "What's stopping us from using CRISPR to gene edit humans to fight disease?" Genetic Literacy Project. April 2, 2018. https://geneticliteracyproject.org/2018/04/02/whats-stopping-us-from-using-crispr-to-gene-edit-humans-to-fight-disease/.
[47] "Statement on Claim of First Gene-Edited Babies by Chinese Researcher." National Institutes of Health. November 28, 2018. https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-claim-first-gene-edited-babies-chinese-researcher.

While the prospect of gene editing for curing disease is promising, use of gene editing technologies on humans is still in its infancy.

Conclusion

The genomics age is upon us and it's an area of rapid innovation with much potential to drastically improve health outcomes. However, it is also an area in which purchasers should tread carefully, ensuring they offer access to appropriate genetic tests while considering the benefits and challenges of testing. The tests that purchasers offer and reasons they offer them may differ by purchaser. For example, one purchaser may offer access to a limited panel that aligns with medical policy and another may decide to offer greater access because it believes the tests engage employees and their families in improved health and better prevention. However, access to testing is not the only consideration, as purchasers should also ensure that their employees and their families have access to the necessary knowledge and support to consent to a test, interpret its results, and plan next steps based on its findings.



Catalyst for Payment Reform (CPR) is an independent, nonprofit corporation on a mission to catalyze employers, public purchasers and others to implement strategies that produce higher-value health care and improve the functioning of the health care marketplace. CPR derives momentum from its membership, a group of 30+ progressive employers and other health care purchasers who collaborate to advance health care payment and delivery reforms, innovative benefit and provider network designs and transparency on costs and quality in the health care system. CPR develops tools, conducts research, and offers education to help purchasers work collectively to push for higher-value health care.

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