

## Genetic Information

Dear Client,

Since the successful mapping of the human genome more than a decade ago, genetic analysis is becoming significantly cheaper, incrementally more informative, and increasingly popular with consumers. Portions of the genome can now be analyzed to detect current and potentially future gene-based health risks and for some types of cancer, it can be used to tailor “precision” medical therapies. These tests and their outcomes are creating important considerations for insurers – especially in underwriting and claims.



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## What is Genetic Testing?

A genetic test can be defined as the analysis of DNA, RNA, chromosomes, proteins, and metabolites and other biological material in order to detect heritable risks, traits, and conditions. Genetic tests can be used for clinical and research purposes, and in some cases, to determine the response of an individual to a drug treatment.



Genetic tests done to confirm a clinical history or presentation are termed diagnostic, whereas tests that may indicate the possibility of an individual developing a condition in the future are termed predictive. The predictive accuracy of genetic tests can be quite variable and depends on many factors, including family history and environment. At this point, the reliability and clinical usefulness of predictive genetic tests for diseases influenced by multiple genes (polygenetic) are of limited clinical value but are generally more accurate and have more proven use for diseases influenced by conditions controlled by a single gene (Mendelian disorders), but the technology in that area is growing.

In general, current uses of genetic testing can be categorized into the following broad categories:

- Assessment of individuals with rare diseases
- Individualized cancer treatment
- Pharmacogenomics
- Preconception and prenatal screening
- Population screening for disease risk

## Underwriting Considerations

The ability to use genetic test results varies greatly by country. It ranges from no use at all, including family history, to full disclosure underwriting. In the U.S., for example, the Genetic Information Nondiscrimination Act of 2008 (GINA) expressly prohibits discrimination with respect to health insurance and employment on the basis of genetic information. Australia, on the other hand, permits insurers to ask applicants to disclose information derived from a genetic test. Other countries such as the U.K. prohibit insurers from asking about past genetic testing and results, but if a policyholder makes a voluntary disclosure an insurer is allowed to use such information but only insofar as that information benefits the applicant. There are also special provisions in the U.K. allowing the use of diagnostic genetic tests.

With decreasing cost and increasing availability of direct-to-consumer genetic testing, insurers should be aware of the potential for asymmetric underwriting information, when the applicant is aware of an increased predisposition towards a condition but the insurer may not be allowed to ask for this information or underwrite on the basis of it.

## Claims Considerations

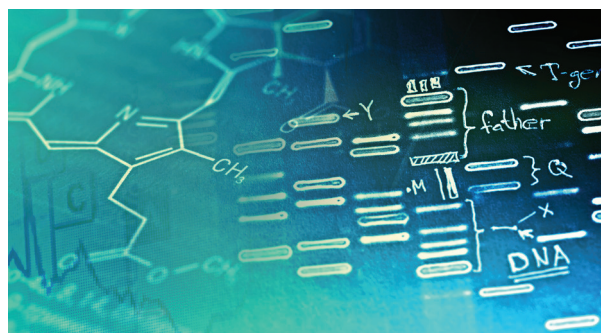
Policy provisions and regulatory restrictions differ in terms of how health insurers address genetic tests. In many cases, predictive genetic tests undertaken due to family histories or in the absence of current pathology might not be covered. However, diagnostic tests in the presence of symptoms, especially if a thorough diagnostic procedure did not elicit a definitive diagnosis, can sometimes be covered.

Preventative medical, surgical or diagnostic procedures on individuals undertaken as a result of genetic test results are frequently not covered as no current disease condition exists. Until recently, few claims requests were seen from policyholders for genetic tests for pre-emptive surgeries in the absence of a diagnosed disease condition. Nowadays, a higher number of such claims is being seen and some insurers are beginning to provide cover for preventative treatment or surgery. Following the high-profile prophylactic double mastectomy undertaken by Angelina Jolie, a limited number of insurers in a few developed markets will now pay for this specific procedure in certain defined circumstances, such as:

- Women diagnosed with breast cancer at 45 years of age or younger
- Women who are at increased risk for specific mutation(s) due to ethnic background (for instance, Ashkenazi Jewish descent) and who have one or more relatives with breast cancer or epithelial ovarian cancer at any age
- Women with a mutation in their TP53 or PTEN genes (TP53: Li-Fraumeni Syndrome; PTEN: Cowden syndrome and Bannayan-Riley-Ruvalcaba syndrome) that place them at increased risk of developing certain cancers
- Women with BRCA1 or BRCA2 mutations, confirmed by molecular susceptibility testing, which increase the risk of breast and/or epithelial ovarian cancer
- Women who received radiation treatment to the chest between ages 10 and 30 years, such as for Hodgkin Disease
- Women with a first- or second-degree male relative who has (or has had) breast cancer
- Women with multiple primary or bilateral breast cancers

- Women with 1st- or 2nd-degree blood relative(s) who have (or have had) multiple primary or bilateral breast cancers
- Women with one or more cases of epithelial ovarian cancer AND one or more first- or second-degree blood relatives on the same side of the family with breast cancer
- Women with three or more affected first- or second-degree blood relatives on the same side of the family, irrespective of age at diagnosis.

Pharmacogenetic testing may be a covered benefit, provided the insured is undergoing the test to determine the most suitable course of drug therapy for a specific disease and the test is considered part of the accepted standard of care. Standards of care can also vary by region and locality. Therefore, the cost of these tests (which can be quite high) are likely to be reimbursable if the health plans provide for it and if the condition for which the genetic test was done was not among the policy exclusions. Specific policy wordings on genetic testing and pharmacogenetic tests help to avoid claim disputes with policyholders.



## Conclusion

Genetic testing is becoming cheaper and is now more commonly performed in the clinical setting. Thus, genetic test results will have a growing impact on how insurers underwrite (when allowed) and adjudicate claims. Insurers will need to keep up to date with genetics advances and technology along with regulatory requirements in order to provide appropriate and high-quality service to clients. This is a task that insurers must do and should be done in good faith and as a result it can demonstrate a commitment to quality and fairness.

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