# The 2008 U.S. Genetic Information Nondiscrimination Act (GINA) Protects Individuals From Discrimination Based on Genetic Test Results

## GINA Coverage[1,2]

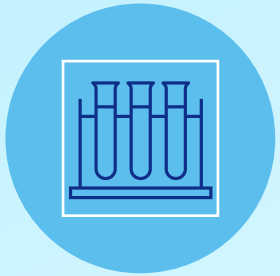
- Genetic information refers to personal and family genetic test results and the manifestation of disease associated with these tests
- A genetic test analyzes human DNA, RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations, or chromosomal changes
- Unlike the ADA, GINA does not protect people already affected by a genetic condition
- GINA Title 1 protects against using genetic information to determine health insurance eligibility or premium or requiring a genetic test to make underwriting decisions
- GINA Title II protects against employment-based discrimination
- GINA does not protect against long-term care, life, or disability insurance discrimination
- GINA does not apply to employers with fewer than 15 employees
- GINA supplements the Americans with Disabilities Act (ADA) of 1990 and the Health Insurance Portability and Accountability Act (HIPAA) of 1996

1. Joly Y et al. *Annu Rev Genomics Hum Genet.* 2020;21:491-507; 2. American Medical Association (AMA). Accessed May 24, 2023. https://www.ama-assn.org/delivering-care/precision-medicine/genetic-discrimination

# 7 out of 8 Insurance Companies Discourage ApoE Testing Due to a Lack of Clinical Utility[1]

"ApoE4 is strongly associated with the incidence and age of onset of AD. Many other genes have shown statistical associations with AD, thus demonstrating some degree of **clinical validity**"[2]

"There is a lack of evidence on the clinical sensitivity and specificity of other genes." Literature searches did not demonstrate how ApoE or TREM2 results might be incorporated into **clinical practice**[2]



No randomized controlled trials compare outcomes of asymptomatic adults at risk for developing LOAD managed with and without genetic testing to demonstrate **clinical utility**[2]

Fewer than 200 CPT codes exist for about 70,000 genetic tests[3]

According to genetic testing frameworks, genetic tests should typically only be considered for clinical use in at-risk populations if they are highly accurate (**analytic validity**), possess suitable positive predictive value (**clinical validity**), and inform medical care (**clinical utility**)[4]

LOAD, late-onset Alzheimer's disease; CPT, Current Procedural Terminology.

1. Arias JJ et al. *Genet Med.* 2021;23:614-620; 2. Blue Cross Blue Shield of Michigan (BCBSM). Effective date July 1, 2023. Accessed May 24, 2023. https://www.bcbsm.com/amslibs/content/dam/public/mpr/mprsearch/pdf/76764.pdf; 3. National Human Genome Research Institute (NHGRI). Published August 15, 2019. Accessed May 24, 2023. https://www.genome.gov/about-genomics/policy-issues/Coverage-Reimbursement-of-Genetic-Tests; 4. Pitini E et al. *Eur J Hum Genet.* 2018;26:605-615.

# Studies Indicate Minimal Psychological Distress After Receiving ApoE Test Results

The largest longitudinal study of DTC service users to date found that only 2% regretted their decision to purchase services and 1% reported any kind of harm as a result[1]

ApoE testing in clinical practice is not recommended based on limited clinical utility, prognostic value in ordinary clinical use, and potential for unintended psychological and social harms (eg, distress, genetic discrimination)[2]

REVEAL and SOKRATES II clinical trial results support the premise that disclosing ApoE results to cognitively unimpaired adults does not cause adverse psychological outcomes[3,4]

Disclosing ApoE results to patients with MCI did not increase anxiety or depression and may provide psychological benefits[5]

Worries about stigma were more common in people with elevated brain amyloid than among ApoE4 carriers. Amyloid indicates a pathologic change. Carrier status alone does not indicate pathology[6]

MCI, minimal cognitive impairment.

1. Roberts JS et al. *Public Health Genomics.* 2017;20:36-45; 2. Langlois CM. *Alzheimers Dement (N Y).* 2019;5:705-716;
3. Largent EA et al. *J Alzheimers Dis.* 2021;84:1015-1028; 4. Christensen KD et al. *Ann Intern Med.* 2016;164:155-163;
5. Christensen KD et al. *Alzheimers Dement (N Y).* 2020;6:e12002; 6. Largent EA et al. *J Law Biosci.* 2021;8:lsab004.