Innovations Potentially Affecting Underwriting: An Initial Review with a Focus on Epigenetics, Medical Tests, and Wearables

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Innovations Potentially Affecting Underwriting: An Initial Review with a Focus on Epigenetics, Medical Tests, and Wearables

Monitoring the Innovation Landscape for the SOA

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Executive Summary

The global doubling of information content has been estimated to occur at a rate of every 12 hours\(^1\), and conceivably faster. This ‘infowhelm’ is a double-edged sword for insurers. While maximization of the global knowledge base can fuel innovation, it can occur only in the context of reasonable cost for a higher benefit.

The insurance industry – underwriters and actuaries in particular – are challenged to constantly examine new innovations that promise to raise confidence and protective value for insurability, within legal limits. This report aims to be the first of several to alert the SOA of promising innovations for the profession.

As an introduction to innovations that directly affect underwriting practice, we will focus in this report on health-related innovations. The beginning section addresses recent developments of combining data sources and models – notably, traditional prescription data with medical claims, and potentially soon electronic health records (EHRs). At least one product in this space has been evaluated for many of the underwriting adoption criteria considered in this report, that will later need to be applied to the remaining earlier-stage innovations: epigenetics, medical tests for cancer and Alzheimer’s Disease, and wearables. The latter earlier-stage innovations should ultimately allow stratified risk scores for the high-cost conditions in the general population – and at insurers. In these sections, we selected four innovative test categories below:

1. **Epigenetic tests**, which confirm health and biological aging status by identifying the epigenetic patterns on the insureds’ DNA, which can change in response to environmental factors (e.g., tobacco use), as well as inherent biological phenomena

2. **Tumor mutational burden (TMB) tests**, which qualify newly-diagnosed patients for high-cure-rate cancer immunotherapies

3. **Blood-based ‘panel tests’ for cancer and Alzheimer’s Disease** that are not germline-genetics based, but correlate with early stage disease or predisposition and, finally

4. **Wearable vital tests** – such as recent FDA-approved cardiac function measurement apps on smartphones

These innovations – coupled with recently legislated freedom for insureds to share their Electronic Health Records (EHRs) voluntarily – provide potential new vistas of data mining for underwriters who will use them in the coming years. Admittedly this report is largely informational for underwriters and focuses on US-based innovations.

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Section 1: Overall Criteria for an Important Underwriting Innovation

In reviews and discussions, the following evaluation criteria for qualifying innovations for adoption by underwriters were selected for this report. These should not be considered firm, nor easily quantified for cost and/or protective value yet, but should increase in confidence with significant data availability over a window of 5-10 years.

**Protective Value**

“Protection” refers to protection from adverse risk by the innovation, with respect to premiums. An innovation that adds protective value – e.g., validated increased risk or lack thereof – will result in better underwriting decisions and more accurate product pricing. For the purposes of this report, innovations are noted that cost roughly $1,500 or less per actionable diagnoses (typical for medical tests) and with cost-reduction likely.

**Efficiency/Workflow**

Efficiency is a judgment of the prospective ease of incorporation of the innovation into the underwriter’s current workflow and speed to decision – wherever possible as an add-on or replacement to current practices without incurring additional labor. For example, can the innovation offering be easily incorporated into the insured’s application, existing medical records, available third-party data sets, or paramedical results?

**Consistency**

An innovation should be robust in its understanding and availability for underwriters, across physiological or behavioral differences among insureds, allowing reasonably similar risk assessment decisions by many underwriters.

**Impact on Sales Cycles/Close Rates**

Momentum to closure is important for selling any product, including insurance policies. Our instantaneous, smartphone-driven world has conditioned insureds along these lines. Underwriters who can assemble the highest confidence innovation tools to rapidly and accurately assess risk will win the sales/close race.

**Regulatory Issues/Fairness**

By its very definition, the purpose of underwriting is to discriminate applicants’ situations for pricing purposes. Lawful practice for insurers allows healthier or lower-risk individuals to be issued policies at lower rates, and unhealthy or higher-risk individuals to be issued policies at higher rates – or be declined coverage entirely. While insurers are not responsible for an insured’s behavior, or pre-existing condition, the industry can enhance fairness by adopting innovations that assist insureds in mitigating unhealthy behaviors that lead to negative underwriting factors. For example, early-warning innovations can be coupled with ‘healthy living programs’ for new policyholders, generating goodwill from insureds and increasing sales from word-of-mouth.

**Reputation/Public Relations (PR) Exposure**

Insurers, like most businesses, fear “headline risk” in mainstream media or social media. Innovations that positively enhance underwriting and also the insureds with effective disease management are a win-win for both parties.

**Fraud Vulnerability**

For innovations to be confidently adopted by both insureds and insurers, they must be trusted and not subject to fraudulent modification or misuse. Third-party verification or approval (i.e., by FDA or HHS) is helpful here.

**Distribution/Adoption**

Will the innovation results be readily accessible (and legally auditable) for both insureds and service providers? Easy distribution to most underwriters and insureds in all regions and for all socioeconomic groups is a desirable attribute for a new innovation. Adoption refers to the ability of the innovation to be both user-friendly and valuable, for both insureds and underwriters, who need to trust the data generated by a new innovation and what the new data says about health risk and future costs to insurers.
Section 2: An Underwriting Innovation in Use Today: Combination of Prescription and Medical Claims

Numerous areas exist for innovations that can streamline underwriting practices. However, one area that intersects well with epigenetics, medical testing, and consumer wearables is the increasing availability to underwriters of combined prescription drug (Rx) and medical claims (Dx) data. This combination will be enhanced further with the increasing real-time availability to actuaries of electronic health records (EHRs).

It is worthwhile to note that the COVID pandemic contributed in parallel to an increased demand for non-paramedical information, especially for life insurance – at a time when face-to-face encounters between customers and agents or paramedical personnel were limited. In response, carriers de-emphasized paramedical requirements and increased the share of policies issued via more automated underwriting tools. Availability of crucial health data without paramedical examination remains of high importance, whenever valid for decisions. Thus, already-available prescription and medical claims/EHR data may grow to replace paramedical exams to a certain extent, along with novel medical and wearable tests covered in the next sections.

An applicant’s prescription history (Rx) provides useful insights into their health and overall life expectancy. Carriers usually aren’t concerned with the occasional round of antibiotics for common illnesses or injuries. However, they do review current/past medications that are taken on a chronic basis by the applicant. Real-time prescription drug histories have been used in life underwriting since 2005, and adoption of this type of data accelerated in the period 2009–2013 to the point that, today, if a carrier is not using it, they are at a major disadvantage relative to their competitors. Real-time prescription drug histories are now well-established, with “hit rates” (the probability that data will be found for any particular applicant) now approaching 90%.²

Medical claims data (Dx) is based on standardized medical billing codes that health care providers submit to insurance carriers for payment. The codes convey information about diagnoses, hospital and physician procedures, inpatient and clinic-administered medications, and medical equipment covered by insurers. This information can provide the underwriters with a fairly comprehensive medical history on many applicants, enabling underwriters to assess mortality risk. This data source is relatively new, but both “hit rates” and adoption are increasing dramatically. Because medical procedure and diagnostic codes are standardized, this structured data is easily used as an input by rules engines and predictive models. This is relevant for evolving cancer and Alzheimer’s innovations.

An evolution of this trend is now available to underwriters, with multiple products from established underwriting data resources (e.g., ExamOne, Milliman) that combines prescription and medical claims data. At least one of these products received independent reviews from multiple unrelated carriers, RGA, Munich Re, and Hannover Re (4-6) (please review these in-depth references for the following charts in this report), which are summarized below in this section as an exemplary application of the evaluation criteria shown above.

2.1 EVALUATION CRITERIA FOR THIS INNOVATION

Protective Value: There is a slight but significant improvement in comparing RxDx to Rx-only data – not scores – relative to best class status (i.e., medical data provided protective value, any time there were adverse findings that would have changed the risk class to anything but best class). However, the carrier who conducted the evaluation did not specify the actual percentage change in its report. Scoring was particularly effective (qualitatively) at segmenting mortality for market-worthy ages 40 to 59, below.

² https://www.rxhistories.com/irix/prescription-data/
Figure 1
PROTECTIVE VALUE ESTIMATE OF PRESCRIPTION AND MEDICAL DATA, BY AGE AND GENDER*

*Please note, for the above figure: In this referenced evaluation, no numeric Y axis was provided. The authors believe, however, that each Y axis line represents 20%, ending at 100% protective value for the highest bar displayed.

A second carrier found that, compared to a prescription-only model, the use of a prescription with medical data model increased the percentage of total risk exposures that can be scored, from 63.0% to 80.4%. The current hit rate, as of late 2022, for the prescription with medical model has increased to 91% according to the product literature, including more recent Dx data sources that became available subsequent to the study.

Efficiency/Workflow: The medical data scores are increasingly available, currently at over 70 carriers. Thus, the combined Rx/Dx data can be implemented without great difficulty and used at a minimum in full, formal underwriting.

Consistency: Prescription and medical data claims generally go hand-in-hand, although errors, rule-out diagnoses, or misdiagnoses, could play a role in a small percentage of cases. These outliers should already be blended into the overall confidence statistics for the product, however.

Sales Cycle/Close Rates: The combination Rx/Dx product particularly assisted Formal Underwriting (FUW) as shown below, with a 51% jump in confidence to reject an applicant (from 139% to 193%). A slight downward drop for passing applicants was seen, from 72% to 68%, when applicants undergo Accelerated Underwriting (AUW).

One of the evaluators illustrated – using a very simplified scenario and using their Actual/Expected (AE) thresholds – that, by switching from an Rx-only to a combined risk score, a carrier can see higher process rates (STP, or straight through processing) and lower mortality of those who passed at the same time.
Regulatory Issues/Fairness: As long as access to medical data remains legitimate and legally available to a carrier, there should be no issues for underwriters in utilizing a combination product – although this situation deserves continued monitoring by underwriters. Ethnic and racial differences through the use of both prescription drugs and medical claims should also be monitored for additional insights.

Reputational Risk/Public Relations: As both data sets are in use and accepted in underwriting, there is minimal risk to reputation or public relations as long as current legal restrictions are respected accordingly.

Fraud Vulnerability: Low risk here is assumed, as both data sets are sourced from licensed professionals (providers).

Distribution/Adoption: Except for data sets controlled exclusively by the product developers themselves, both sets of data should be accessible to insurers, but at more effort to incorporate into in-house rules engines.

2.2 ADDITIONAL HEALTH DATA INPUTS RESOURCES FOR FUTURE UNDERWRITING INNOVATIONS

Electronic Health Records: In 2009, the federal government passed the Health Information Technology for Economic and Clinical Health Act (HITECH) as part of the larger American Recovery and Reinvestment Act (ARRA). HITECH mandated that, beginning in 2014, all health care providers must keep medical charts in an electronic format. The act both incentivized and helped to fund a transition from paper records.

Two important changes occurred just prior to, and during, the COVID crisis. First, all insureds now have a legal right to obtain and, thus, own their individual EHRs and voluntary disclosure from an applicant is not subject to restrictive HIPAA compliance thereafter. This opens an opportunity for insurers to incentivize applicants’ selective disclosure of disease, treatment, and prescription data - either directly or via nonprofits. Secondly, the COVID emergency waived restrictions based on telehealth, with between 32 and 50 million annual doctor consultations.

4 https://www.statnews.com/2022/10/06/health-data-information-blocking-records/
having been done over internet video calls. Both providers and patients have positively embraced this change, which adds another dimension of record-keeping for insureds that can be later disclosed. Adding voluntarily-submitted EHRs – either sourced from individuals or aggregated anonymous data sets – could additionally increase protective value.


In summary, the ability of underwriters to increase protective value using currently available products and newly-legal medical data release is on an upswing, if only an incremental one, provided HIPAA restrictions are avoided. While cost is not available publicly for this innovation area, SOA members can contact the vendors and reflect on this innovation’s utility in light of their current internal prescription and medical claims databases and risk scores.
Section 3: Landscape for Underwriting Innovations: Epigenetics

Epigenetics doesn’t change the genetic code – it reveals the biological changes that occur naturally in response to environmental and intrinsic cues.

Epigenetics refers to biological phenomena that influence gene expression without affecting the inborn genetic code. This is important as inborn genetic code-specific information is restricted from use by insurers via the 2009 HITECH Act. More specifically, epigenetic biomarkers represent distinct patterns of methylation (i.e., the enzymatic addition and/or removal of carbon and hydrogen atoms) on DNA that are indicative of aging, health, and lifestyle behaviors (e.g., smoking, exercise, diet, and alcohol use). Epigenetics can be measured robustly in many different cell types. For underwriting, blood or saliva samples are likely preferred sources.

Epigenetic biomarkers could be used in numerous ways during underwriting. Use cases include, but are not limited to, (i) providing novel health information that can add additional value to current medical underwriting, (ii) replacing traditional underwriting information and (iii) triaging applicants to improve time to issue for healthy applicants.

For this report, we are focusing on two innovative epigenetic biomarkers that are currently available for commercial use to show the potential uses of epigenetics in the insurance industry: biological age and tobacco use.

3.1 EPIGENETICS INNOVATION #1: BIOLOGICAL AGE

3.1.1 DESCRIPTION

Biological age represents the idea that individuals may be aging faster or slower than their chronological age indicates. Several epigenetic clocks have been developed as a method for determining an individual’s biological age. Technically speaking, biological age represents a mortality risk score that is relative to other individuals of the same chronological age. Biological ages above chronological age indicate a higher mortality risk, while the opposite is true of biological ages below chronological age.

The details in the following section will focus on the GrimAge epigenetic clock developed in 2019 by UCLA professor, Dr. Steve Horvath. GrimAge has shown the strongest relationship with all-cause mortality among the various epigenetic clocks studied to date. Other epigenetic clocks are available, however, and can be evaluated using similar criteria.

GrimAge was developed using the Framingham Heart Study and validated in a number of independent studies. When controlling for chronological age and sex, a one-year increase in GrimAge resulted in a 10% increase in mortality risk. Further analysis controlling for other known mortality risk factors (body mass index, educational level, alcohol intake, smoking pack-years, prior history of diabetes, prior history of cancer, and hypertension status), in addition to chronological age and sex, showed a one-year increase in GrimAge to indicate a 9% increase in mortality risk. Thus, GrimAge was highly associated with all-cause mortality, even taking into account for some mortality risk factors – and the mortality risk compounds for every additional year of GrimAge.
3.1.2 EVALUATION CRITERIA

Protective Value: The protective value of a biological age will vary based on the use case. Biological age represents a novel measure of health that could be used for any of the three use cases (i – iii) described above in the overview section. Each use case would result in a different impact on the expected number of claims given the other underwriting information available. GrimAge can most effectively differentiate mortality risk in a targeted triage use case where there is a lack of biological information. GrimAge can also be used to further differentiate mortality risk in addition to traditional underwriting information (e.g., a paramedical exam), but the presence of additional information will reduce slightly GrimAge’s effectiveness from 10% to 9% increased risk of mortality per one-year increase.

The cost of obtaining biological age using an epigenetic clock, such as GrimAge, is an important consideration for determining the protective value. The technology used to extract the epigenetic information necessary for calculating GrimAge is relatively new and expensive. The technology is similar to the technology used by genetic testing companies, such as 23andMe and Ancestry.com. Its cost is expected to reach a similar price point (e.g., roughly $200 for data only, inclusive of processing cost) as technology matures. Further studies will be necessary to quantify the exact protective value of biological age based on the specific use case and context.

Efficiency/Workflow: Biological ages can be efficiently fit into the current underwriting process, as it can be obtained from either a saliva or blood sample. The necessary samples could be collected during the usual paramedical exam or, in the case where there isn’t a paramedical exam, via a saliva collection kit supplied directly to an agent or consumer to be self-administered. Lab processing currently takes one to two weeks at this time, and results can easily be accessed via underwriting engine or a manual review.

Consistency: Utilizing biological age in the underwriting process should result in more consistent evaluation of risk because it represents a single quantitative measure of biological mortality risk. A single quantitative measure of risk leaves less judgment for underwriting, compared to utilizing multiple measures of biological risk.

Sales Cycle/Close Rates: A biological age assessment could positively impact the closure rates in a variety of ways. As previously mentioned, biological age can be obtained through a saliva sample and remove the need for more invasive blood and urine collection for certain cases. Biological age also represents an aggregate measure of health that can be more quickly assessed by an underwriter resulting in faster underwriter decisions. Biological age could also lead to more personalized pricing, resulting in more accurate rates that can be passed on to the consumer or to the agent through higher commissions.

Regulatory Issues/Fairness: Biological age is determined by a predictive model that uses epigenetic information as an input. Like all predictive models, there is the potential for bias based on the data used to build the model. GrimAge has been validated in multiple data sets that included both sexes and multiple races/ethnic groups. The regulations around predictive models in underwriting are rapidly changing, however, and additional studies may be necessary for regulatory approval.

Reputational Risk/Public Relations: There is manageable reputational risk involved in implementing biological age assessment via an epigenetic clock. The primary concern is the confusion around the differences between epigenetics and genetics. In general, the public responds negatively to genetic testing in underwriting, and additional educational efforts will be necessary to ensure there is a proper understanding of the differences between dynamic epigenetics and hereditary genetics. The field of epigenetics is growing rapidly and is expected to become mainstream over the next decade, which will reduce reputational risk.
Fraud Vulnerability: Fraud vulnerability of biological results overall is generally low, but also dependent on the collection method. Utilizing a paramedical vendor represents the lowest risk of fraud at an increased cost. Self-collection represents the largest fraud risk, but additional guardrails can be put into place depending on a carrier’s risk tolerance. Examples of guardrails include a virtual visit during sample collection, verifying chronological age and sex based on epigenetic data, and DNA fingerprinting.

Distribution/Adoption: Distribution will be available either through traditional paramedical exams or through a direct-to-consumer self-collection model. Biological age testing has not been adopted by the life insurance industry, but there are multiple companies in the space creating the infrastructure necessary to complete biological age testing effectively and efficiently at scale.

3.2 EPIGENETICS INNOVATION #2: TOBACCO USE BIOMARKER

3.2.1 DESCRIPTION

Quick Link Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5653254/

Misrepresentation of tobacco use represents a large driver of increased mortality within the life insurance industry. A recent study published by ExamOne indicated that misrepresentation of tobacco use represents a cost of over $4 billion to the life insurance industry.

There are multiple approaches to identifying tobacco use through the epigenome. One approach involves measuring the amount of methylation, a specific type of epigenetic mark, on a single location on the epigenome. More recent advances for tobacco use determination include utilizing multiple epigenetic sites and machine learning algorithms.

The remainder of this section focuses on identifying tobacco use through a single location on the epigenome. Specifically, the epigenome location known as cg05575921 has a narrow biological “set-point,” with non-smokers often having methylation levels at that site between 80% and 90%. Utilizing cg05575921 as a classifier for tobacco use proved to be effective in multiple studies (e.g., AUCs, or confidence levels, ranging from 0.87 to 0.90).

3.2.2 EVALUATION CRITERIA

Protective Value: As with any technology, the protective value of using an epigenetic tobacco biomarker in the underwriting process is highly dependent on use case. As an add-on to cotinine (a nicotine byproduct in the body) testing, the epigenetic tobacco use biomarker likely does not return much value in its current state. As a replacement for cotinine, an epigenetic biomarker would likely return similar or better protective value compared to cotinine.

One unique advantage epigenetics has over cotinine is how long into the past it can assess tobacco use after tobacco use is stopped. Cotinine has a relatively short half-life (around 19 hours), meaning that cotinine levels will be undetectable within a few days of stopping tobacco use. This makes cotinine vulnerable for tobacco misrepresentation. Further studies are necessary to determine the exact length of time that epigenetics can be used to determine tobacco use, but early studies have shown a slow reversion as early as one month of stopping tobacco use. On the other end of the spectrum, numerous independent studies have demonstrated the ability of epigenetics to identify individuals that quit smoking decades ago. As a more persistent biomarker of tobacco use, epigenetics

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6 https://blog.examone.com/blog/2023/01/25/life-insurance-laboratory-collaboration-tobacco-study/
has the additional promise to refine the nuances of “non-smoker” and reduce smoking misrepresentation using a quantitative biomarker.

These advantages need further research to quantify exactly how they will impact the protective value, but the promise of epigenetics for assessing tobacco use represents an opportunity for tremendous protective value.

**Efficiency/Workflow:** An epigenetic biomarker for tobacco use will easily fit into the current underwriting workflow. The epigenome can be measured in either blood or saliva. Collection can be done during a standard paramedical exam or self-collected by the applicant. Lab results can be provided in a similar method to lab results today.

**Consistency:** Like any lab test, the cutoffs used to classify applicants into tobacco classes and non-tobacco classes will vary from company to company. Once an appropriate cutoff is determined, the same underwriting decision should be achieved regardless of who is underwriting the case.

**Sales Cycle/Close Rates:** A saliva-based collection approach could be used to improve the customer experience and improve close rates when compared to traditional paramedical exams. A blood-based collection approach, utilizing a paramedical exam, likely would not have a positive or negative impact on the sales cycle.

**Regulatory Issues/Fairness:** There is some regulatory risk due to many people being unfamiliar with epigenetics. With proper education, regulators should view an epigenetic tobacco biomarker similarly to measuring an applicant’s cotinine levels to determine tobacco use. In terms of fairness, further analysis is needed to determine if there is a meaningful difference in specific methylation levels based on sex, race, or protected class.

**Reputational Risk/Public Relations:** Like biological age, there is manageable reputational risk involved in implementing an epigenetic biomarker for tobacco use. The primary concern is a confusion around the differences between epigenetics and genetics. In general, the public responds negatively to genetic testing in underwriting and additional educational efforts will be necessary to ensure there is a proper understanding of the differences between epigenetics and genetics. The field of epigenetics is growing rapidly and is expected to become more mainstream over the next decade, which will reduce reputational risk.

**Fraud Vulnerability:** Fraud vulnerability of an epigenetic tobacco use biomarker is generally low, but also dependent on the collection method. Utilizing a paramedical vendor represents the lowest risk of fraud at an increased cost. Self-collection represents the largest fraud risk and additional guardrails can be put into place depending on a carrier’s risk tolerance.

**Distribution/Adoption:** Distribution will be available either through the traditional paramedical exam or through a direct-to-consumer self-collection model. An epigenetic biomarker for tobacco use is currently available for commercial use, but is not widely adopted by the life insurance industry.
Section 4: Landscape for Underwriting Innovations: Medical Tests

4.1 INTRODUCTION

Medical Tests comprise only 2% of total healthcare spending, but influence ~65% of clinical decisions.

For the purposes of this report, a medically-ordered test is defined as a data gathering tool that must have these essential elements:

a) measures a valid biomarker(s) for an insured’s physiological status, subject to regulatory oversight
b) results in an actionable diagnosis, prognosis, or treatment (or to slow progression/pain if untreatable)
c) does not involve a requirement for a dedicated expensive instrument.

Numerous tests in commerce or development do not possess these elements and, thus, are not part of this section. The insurance industry benefits from medically-ordered tests as they are pre-screened, approved, or otherwise scientifically validated for the medical profession by either FDA or HHS rule (or similarly by other governments). Innovative tests in development that reveal pre-approval data that will likely match the three elements above are, thus, also considered candidate innovations.

For the purposes of this report, here and in the next sections, the following list of diseases and their 2021 US mortality (deaths) were a focus, where innovations could offer potentially the highest impact for insurers and underwriters. Exemplary innovations in this section are focused on the bolded chronic diseases (Source: CDC) most in need of innovation and tools that can add protective value. (Note: Cardio/stroke and accidents are covered later.)

Heart disease/stroke: 857,226
Cancer: 602,350
COVID-19/infectious diseases: 404,375
Accidents (unintentional injuries): 200,955
Chronic lower respiratory diseases: 152,657
Alzheimer’s disease: 134,242
Diabetes: 102,188

4.2 OVERALL EVALUATION CRITERIA FOR MEDICAL TESTS

Protective Value: Greater (or novel) accuracy in disease identification and/or stage of progression provides the industry with greater certainty of treatment and their costs. For example, although imperfect, the PSA blood test and the BNP heart failure blood test continue to provide clearcut guidance on treatment. (Ideally, an innovative test will result in treatment changes that could result in at least $10,000 in net savings per positive data result, versus absence of tests and, thus, the current standards of care. However this is hard to estimate at this time with most innovations listed in this report.)

Efficiency/Workflow: Medically-ordered tests with the essential elements listed above (a-c) should generally take no more than 48-72 hours, with a total cost of under $1,500 per test using either existing or no equipment. Regulated testing infrastructure exists to easily incorporate the innovative tests for use by providers and later underwriters.


https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7745157/

Test results should be easily added to underwriting, especially for life insurance. Novel medical test results can potentially be cross-confirmed by prescription and claims history changes over time, as shown in section 2.

**Consistency:** During the early adoption period for a medical test, differences in medical opinion are expected, thus, inconsistency should initially be tolerated by insurers, but should settle over time. Innovative medical tests, however, that are convincing statistically (e.g., \( p = .01 \) or less) with clinical data will shorten this period, as providers will not risk malpractice exposure. [https://www.jacr.org/article/S1546-1440(11)00357-7/fulltext](https://www.jacr.org/article/S1546-1440(11)00357-7/fulltext)

**Sales Cycle/Close Rates:** Novel medical tests should result in more accurate cost forecasts and savings for both health professionals and insurers by reducing uncertainty in treatment and outcomes. In turn, the industry can confidently and quickly price premiums without extensive underwriting considerations, leading to faster close rates.

**Regulatory Issues/Fairness:** Racial and ethnicity-based clinical data availability remains uneven, and is a noted disparity in much of healthcare, including regulatory agencies. Innovation developers and the industry are acutely aware of this and pay greater attention or risk increased scrutiny from regulators. As FDA or HHS approval is required for medically-directed tests, and these agencies are sensitive to ethnic inclusion, regulatory and fairness issues should evolve to be minimal for new medical test innovations.

**Reputational Risk/Public Relations:** This, in general, follows regulatory status just discussed above.

**Fraud Vulnerability:** Similarly, fraud vulnerability is low for medical tests that are subject to FDA or HHS regulation.

**Distribution/Adoption:** An oligopoly in medical testing is somewhat present via LabCorp and Quest Diagnostics, however, distribution is excellent and now includes many successful breakthrough companies, such as Exact Sciences (ColoGuard), that have arrived on the scene, and there are over 1500 accredited laboratories operating under HHS rules that generate one million test results per year (source: Laboratory Economics). In addition, new players exist, such as Apple and Amazon, along with increased telehealth driven by regulatory leniency during the COVID pandemic. These players increasingly offer FDA-approved at-home or even retail tests (Walmart QuestDirect alliance) and results that insureds can release voluntarily.

4.3 INNOVATIONS SELECTED FOR UNDERWRITING EVALUATION – CURRENTLY OR IMMINENTLY ON THE MARKET

4.3.1 MEDICAL TEST INNOVATION #1: TMB – TUMOR MUTATIONAL BURDEN TEST (>10 MUTATIONS → IMMUNOTHERAPY RX)

4.3.1.1 DESCRIPTION

Figure 3
TMB IS A KEY INDICATOR FOR RESPONSE TO IMMUNOTHERAPY

![TMB: Immune Checkpoint Indication for Response](source)

Source: Caris Life Sciences

[Note: This innovation was studied initially in the 2019 SOA article on Cancer Genomics, and is due for an update](https://www.soa.org/resources/research-reports/2019/cancer-genomics/)

What is the Innovation?

- A lab test that uses ‘blinded’ genome sequencing of tumor cells, that simply counts mutations in a pre-selected stretch of the genome: the higher number of mutations, the greater chance for immunotherapy success
- TMB is reported as the number of mutations in a given stretch of tumor DNA (#mutations per megabase)
- TMB of 10 or greater mutations have drastically lower morbidity and mortality upon treatment with novel immunotherapy drugs (e.g., Keytruda or OPDIVO)
- Innovators at Memorial Sloan Kettering are also adding a simple blood cell count to add confidence
- Cost estimates for this test fall below the evaluation criteria ceiling of $1500

Quick Link References

Journal of American Medical Assoc., Dec 2020

Sloan Kettering Studies on TMB
[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7796993/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7796993/)
EVALUATION CRITERIA FOR THIS INNOVATION

Protective Value: Standards of care costs for lung cancer are substantial, estimated at over $150,000 per patient. Lowering costs – especially surgical and collateral health issues – and improving quality of life with a potentially curative treatment via TMB and immunotherapy is increasingly plausible. Multiple drugs in this class will compete on price in the near future (and, in the long run, as generics). The combination of TMB and immunotherapy was cost-effective or cost-neutral for lung cancer and melanoma in the 2019 analysis for SOA, cited above.

Efficiency: The TMB test has a turnaround of no more than 72 hours from competitive laboratories, resulting in rapid evaluation and treatment strategies by oncologists. Thus, timing and adoption by oncologists will be rapid and reflected in changes in claims for the industry, at least in lung cancer and melanoma. Underwriters can ask applicants if TMB-immunotherapy occurred, plus correlate prescription histories/claims for additional data mining.

Effect on Workflow: A TMB test inquiry can be included in claim pre-authorizations at a minimum, as a simple addition without any delay in review time, leading to a potentially lower time commitment for overall reviews.

Sales Cycles/Close Rates: Insurers who adopt TMB coverage ahead of competitors may be able to have an advantage in policy sales, close rates, and overall payouts – especially for oncology claims. TMB’s importance in underwriting is largely for current insureds admittedly – not for new healthy applicants.

Consistency: TMB is currently conducted in HHS-regulated laboratories for clinical decisions by oncologists. FDA approvals are also in place, particularly for Foundation Medicine (Roche). Clinical research – especially at Sloan Kettering (NYC) – has shown TMB plus immunotherapy’s utility for predictive survival\(^9\). However, multi-site laboratory and clinical comparator studies are still lacking, and this is complicated by what drug choice is made by clinicians (usually Keytruda or OPDIVO). Consistent benefit matched to cancer type and drug choice is not yet in place, but is being published diligenty by clinical researchers.

Fairness: Racial and ethnicity effects are a disparity in much of healthcare, and ethnicity data remains to be gathered for TMB-driven immunotherapy of cancer. It is noteworthy that individuals subsidized by government funding undergo novel immunotherapies more than Medicare patients (and likely individual or group insureds).

Regulatory Issues/Fairness: As FDA or HHS approval is required, regulatory and fairness issues are minimal.

Reputational and Public Relations Exposure: This, in general, follows regulatory status discussed above.

Fraud Vulnerability: Similarly, fraud is minimal for tests subject to FDA or HHS approval.

Distribution/Adoption: An oligopoly in medical testing is somewhat present via LabCorp and Quest Diagnostics, however, many successful breakthrough companies, such as Exact Sciences and Foundation Medicine (both leaders in TMB), have arrived on the scene. Underwriters currently access data via claims from these sources.

4.3.2 MEDICAL TEST INNOVATION #2: AN ALZHEIMER’S DISEASE RISK BLOOD TEST

4.3.2.1 DESCRIPTION

What is the Innovation?
A simple blood test to determine the risk of developing Alzheimer’s disease, focused on three factors: plasma amyloid β, apoE protein, and the age of the patient.

Quick Link Reference

4.3.2.2 EVALUATION CRITERIA

Protective Value: Alzheimer’s annual healthcare costs in the US total over $300 billion, across roughly five million individuals, and are expected to reach $1 trillion at the peak risk for aging Baby Boomers. An innovation in testing that can start low-cost interventions for Alzheimer’s Disease earlier than standard of care is expected to forestall high-cost later stages – bringing profound protective value.

Efficiency: A medically-ordered blood test can be completed within a week, and potentially sooner, with a cost under $1,300 per test currently, and results are equal to or more definitive – and less expensive – than a PET scan. Incorporating this add-on blood test into medical exams for underwriters could be highly advantageous for both intervention and profitability/cost savings.

Effect on Workflow: An early Alzheimer’s inquiry can be included in underwriting pre-authorizations without any severe delay in review time, and potentially lower time commitment for overall reviews. Incentives could help participation, at least for the first 100 or more participants for a tracking study.

Sales Cycle/Close Rates: Underwriters adopting this test may have substantial advantages in sales and close rates – at a minimum in adding protective value for their products.

Consistency: The test is new, thus, underwriters should expect differences in medical opinion – but also competitive tests that reduce costs. Consumer resistance may be more intense (‘don’t want to know, I’m fine’). Innovative tests that are statistically sound (e.g., p < .01) will shorten this period as providers will not risk malpractice exposure.

Fairness through Distribution categories: same as for the TMB Innovation

4.3.3 MEDICAL TEST INNOVATION #3: AN ALL-CANCER BLOOD TEST

4.3.3.1 DESCRIPTION

**Early Cancer Detection Test Studied at Mayo Clinic**

June 4, 2021

Mayo Clinic today recognized a multi-cancer early cancer detection (MCED) test called Galleri™ that can detect more than 50 types of cancers through a simple blood draw. The Galleri test is intended to complement U.S. guideline-recommended cancer screenings. Mayo Clinic Oncologist Minetta Liu, M.D. was involved in the development of the new test.

What is the innovation?

- A blood test that screens for DNA fragments representing more than 50 types of cancer
- Alerts your doctor if you have a signal for a cancer, and indicates which organ is possibly the source
- Interim results from a clinical trial involving 6,000 people over age 50 showed that the test helped diagnose 29 who didn’t know they had cancers of the lung, ovary, rectum, neck, breast, and pancreas
- This "liquid biopsy" is intended to supplement other available screening tools, is on a fast track to FDA approval, but is already HHS-lab approved and available now for $949 with a doctor's prescription.

Quick Link References


Walmart-Quest Alliance for At-Home Tests: [https://walmartquestdirect.questdiagnostics.com/products](https://walmartquestdirect.questdiagnostics.com/products)

4.3.3.2 EVALUATION CRITERIA FOR THIS INNOVATION

**Protective Value:** The example product studied here – Galleri – is an early indicator of cancer risk and, thus, an early prognosis aid, unlike TMB which has an actionable treatment outcome. As such, it's protective value is less certain pending significant data aggregation and multi-center clinical trials. However, the ease of a blood test and the scope of cancer types is a major advance pending this data – along with the backing of Mayo Clinic.

**Efficiency:** Blood tests generally take no more than 72 hours, with a cost under $1,000 per test. Time to results take a week or more, as there is no pressure on a treatment decision. This could affect underwriting adoption.

**Effect on Workflow:** As an initial screen, it is currently less useful and adds slight delays for underwriting.

**Sales Cycles and Close Rates:** This may be controversial, as cancer is a feared and common affliction – and applicants may go to other carriers that would not require the test, requiring strategic marketing approaches.

**Consistency:** The test is relatively new, thus, differences in medical opinion are expected in the years ahead. In addition, as before, consumer resistance may be more profound (‘I don’t want to know’). Again, tests that are

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convincing statistically ($p = .01$ or less) will shorten this period, as providers will not risk malpractice exposure.

**Fairness through Distribution categories:** same as for TMB
Section 5: Landscape for Underwriting Innovations: Wearables

5.1 INTRODUCTION

“We have more sensors on our cars than we have on human beings.” – Dr. Michael Snyder, Stanford

For the purposes of this report, a healthcare wearable is a data gathering tool that has these essential elements:

a) measures a validated physiological signal or event on a wearable internet-connected device
b) results in an actionable diagnosis, prognosis, or treatment response
c) is nearly-constantly attached to the insured for operation.

Numerous wearables in commerce or in development do not possess all these elements, including admittedly the largest class as well: the fitness metrics wearables. However, wearable devices apps are now pre-screened and marketed for the medical profession via FDA or HHS in the United States, and similar agencies in other governments.

The following list of diseases again details 2021 US mortality and, thus, offers guidance on those Wearable Innovations that could have a high impact on the industry. Exemplary innovations are focused on the **bolded** diseases (Source: CDC) below that are chronic and believed to be most in need of innovation. (Note: Diabetes wearables for blood glucose are well established, thus are not considered an innovation for this report.)

**Heart disease/stroke:** 857,226  
Cancer: 602,350  
COVID-19/infectious diseases: 404,375

**Accidents (unintentional injuries):** 200,955  
Chronic lower respiratory diseases: 152,657  
Alzheimer’s disease: 134,242  
Diabetes: 102,188

The healthcare industry is expected to monitor the health of an estimated five million patients via wearable devices this year (2023), driving $20 billion in annual spending on eligible devices alone – and, with new apps and approvals, should reach $139 billion by 2026\(^\text{12}\). Deloitte - in a recent report (2022) - estimates a 19% growth rate, which is held back largely by provider and privacy concerns. Some of the main issues surrounding wearables are summarized below, along with some supportive weblink references.

Roughly 30-40% surveyed use Healthcare Wearables, compared to a 71-90% smartphone customer base  
[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7600024/?report=printable](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7600024/?report=printable)  

Concerns remain with provider organizations - trust and data/HIPAA issues  

Deloitte, in particular, has intensively studied wearables’ data and the potential impact on healthcare:  

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\(^{12}\) [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7600024/?report=printable](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7600024/?report=printable)
5.2 EVALUATION CRITERIA

Protective Value: Providers’ access to a real-time health event of an insured - outside of a clinical setting - is a novel data source for both the provider and potentially insurers. As one example, most insureds are eager to have a ‘911-like’ immediate internet-driven call-out of a potentially fatal event sent to providers or emergency responders, especially if they are not conscious at the time. Protective value savings for the industry will be maximized by reducing long-term high cost claims thanks to a shortened time to medical intervention by EMT professionals.

Efficiency/Workflow: Life-threatening data gathered in a smartphone or other accessory device, and reported via a downloaded subscription app, can avoid extensive morbidity compared to standard of care. Speed of treatment is especially important for heart attack and stroke. At a maintenance level, insureds can adjust themselves to risky activities based on, for example, a cardiac function app alert – and learn to avoid those activities, further reducing claims. Use of wearable apps can easily be added to underwriting questionnaires.

Sales Cycles/Close Rates: Incentivizing applicants to purchase the app may result in higher sales and close rates.

Consistency: During the early adoption period, differences in medical opinion on performance and the app’s practical use in medicine are expected, but should settle over time. Innovative wearable performance that is convincing statistically (p = .01 or less) with clinical data will shorten this period, as provider organizations will not risk malpractice exposure. Insureds’ compliance is critical, as smartphones can be shut off or put in airplane mode.

Regulatory Issues/Fairness: FDA-approved wearables avoid regulatory risk. Racial/ethnicity effects have been a disparity in much of healthcare. Broad use of smartphones across all the population should reduce these and other fairness issues. Discounted subscriptions for protected classes for wearables apps may additionally help correct any documented disparities, including refurbished free smartphones for low-income groups.

Reputation/Public Relations: This should follow regulatory status as just discussed above, except for proprietary software code and certain data aggregation practices that might attract criticism.

Fraud Vulnerability: Similarly, fraud is minimal for wearable data subject to FDA or HHS approval. While theoretically wearable health data hacks are possible, there are no substantive reports at this time and incentive for such hacking would appear to be lacking (unless perhaps for public figures). Biometric or correlated readouts at provider institutions will assist – but not eliminate – the potential for ‘handing off to a healthy friend’ issues.

Distribution/Adoption: If an insured maintains a smartphone or a smart watch, distribution and adoption of an app is an extremely low barrier to overcome (including low-income incentives by the government or industry).
5.3 WEARABLE INNOVATION #1: ELECTROCARDIOGRAM APP IN CREDIT CARD FORMAT (FDA-APPROVED)

5.3.1 DESCRIPTION

What is the Innovation?

- A credit card sized sensor for FDA-quality electrocardiograms, in seconds
- Bluetooth enabled, no Wi-Fi required for remote readings (later reportable, however)
- EKG reviews by a cardiologist are offered
- FDA approval occurred in early 2022
- At least one product is available on Amazon – outstanding consumer reviews
- Costs are well-below the criteria threshold, generally under $200

For an overview of this product class, see the product information at this link:
https://store.kardia.com/products/kardiamobile-card
https://www.amazon.com/KardiaMobile-Card-Wallet-Sized-Personal-Device/dp/B09TQ3ZN8V

Overall, the ability to consistently monitor a heart condition is very helpful to afflicted insureds, who are concerned about episodic changes and having better control over their behaviors and activity (e.g., ‘biofeedback’). While extensive data remains unavailable for underwriters to adopt this innovation, the next 5-10 years should reveal a distinct difference in health outcomes for users versus non-users. For example, in 2020, a study found that continuous monitoring using an EKG app recorded double the number atrial fibrillation events than frequent, but intermittent, EKGs. https://pubmed.ncbi.nlm.nih.gov/32995870/

The addition of a question to all applicants asking if they currently utilize a cardiac app would be easy for underwriting groups to adopt. In the meantime, health economic studies by research institutes and industry should backfill meaningful statistical data on cost savings among users and non-users.

For an excellent review article on the utility of wearable cardiovascular innovations with clinician, also see this reference. Impressive data on the survival of life-threatening cardiac events using mobile apps, versus non-use, is critical for underwriters in considering future adoption of this innovation.
https://www.nature.com/articles/s41569-021-00522-7
5.3.2 EVALUATION CRITERIA FOR THIS INNOVATION

**Protective Value:** The convenience of monitoring one’s heart status with FDA wearable devices and/or apps – especially when there is an established risk for the insured or by extension their immediate families – is a major new cost-saving tool for said insureds, providers, and the industry. FDA-valid data is real and useful, even though, in the short term, tests would be repeated in provider offices until the data is trusted by the medical community. In an emergency, time matters, and advanced preparative countermeasures by emergency med tech personnel and providers should minimize heart damage and claim costs in the medium-long to the industry. Although a credit card device is chosen for this innovation, multiple other formats exist (i.e., wire leads into smartphones).

https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211668.pdf  

**Efficiency/Workflow:** Questionnaires can ask about an insured’s use of wearables, and, in parallel, if they have underlying or familial cardiovascular conditions.

**Sales Cycles/Close Rates:** Discounted app/devices may boost sales for certain customers and attract more sales.

**Consistency:** At present, there are risks for slow adoption by providers despite the FDA approvals of the app. This is due to provider policies, and fear of untrained use and/or errors in the app software, including hacker risks. While outlier risks may always be present, secure connections, biometrics, and software controls should result in clinical benefit of use to providers and the industry.

**Regulatory/Fairness:** Regulatory approval is a prerequisite for this innovation. App and hardware costs (especially using existing smartphones) are minimal, thus broad availability to insureds can be established in the next few years and be independent of income or racial differences.

**Reputation/Public Relations:** There is believed to be low exposure risk in this area, except for connectivity issues.

**Fraud Vulnerability:** There is no benefit to hackers to disrupt this innovation in the general population, thus, the risks are believed to be low. Users should be self-motivated, as false reporting could prove fatal. Multiple biometric-secure readouts coupled with clinical EKGs should eliminate fraudulent practices by users, e.g., signing in and having a healthy person use the app.

**Distribution/Adoption:** There is wide availability for the entire population at present for compatible apps, across all socioeconomic levels. Underwriting data can be obtained by questionnaire and claims data, compared to non-users.
5.4 WEARABLE INNOVATION #2: FALL DETECTION APP

5.4.1 DESCRIPTION

What is the Innovation?

Similar to step counts, a smartwatch (and possibly soon a smartphone) can record a large body movement that can be correlated with a fall that would risk consciousness or indicate a stroke or other cardiac event. Falls occur in 30% to 60% of older adults each year, and 10% to 20% result in injury, hospitalization, or death\(^{13}\) (Rubenstein, 2006). For the elderly, falls cause 4-12 day hospital stays per event\(^{14}\) (Bouldin et. al., 2013).

As before in use of a cardiac app, by adding a question to applicants over 50 about whether they do – or would – use such an app could be easy for underwriting groups to adopt. In the meantime, scientific studies at wearables research institutes would expand on the incident and cost differential between users and non-users.

Quick Link References
(Note: Critical clinical studies remain small, based on a PubMed search)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8519485/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8050745/

5.4.2 EVALUATION CRITERIA FOR THIS INNOVATION

Protective Value: Assuming fall detection and dial-out capability are generic features for smartphones (as seen for step counts), this innovation could be a nearly cost-free increase in protective value for the industry. By alerting emergency medical personnel for a faster response to an unconscious (or other) falling event for an insured, precious recovery time is gained that minimizes brain bleed and pressure buildup. Admittedly, bodily/bone injuries will likely not see any protective value increase.

Efficiency/Workflow: This is a non-regulated question that can be immediately added to underwriting questionnaires (e.g., ‘Do you use an active fall detection and call out app on your smartphone?’).

Sales Cycle/Close Rates: Discount coupons for Apple watches/apps could raise close rates and sales.

\(^{13}\) https://pubmed.ncbi.nlm.nih.gov/16926202/
Consistency: Substantive data aggregation awaits further analysis, which could be affected by regional emergency response times/staffing shortages. Still, logically this remains a potentially cost-free underwriting request.

Regulatory Issues/Fairness: No regulations for fall detection; but device/app providers unlikely will issue a warranty. This innovation is also available for Samsung smartwatches. Donated smartphones can reach all of society.

Reputation/Public Relations: Insurers who adopt this approach may get heightened publicity/goodwill.

Fraud Vulnerability: Unlikely, as there is no economic incentive to hack this feature. However, sudden acceleration (e.g., roller coaster or conscious fall) could create a false alarm and might affect app usage.

Distribution/Adoption: See Regulatory Issues/Fairness above.

5.5 DISCUSSION AND OVERALL SUMMARY FOR THIS REPORT

A regular mechanism to evaluate new innovations for underwriters is desirable for the SOA, its members, and the industry. This report – focused largely on medical and wearable innovations – is potentially the first of several to address this opportunity, drawing upon expertise both within and outside the actuarial community.

In this publication, leading-edge medical tests and epigenetics were considered and covered with a bias toward high-incidence, chronic, and high-mortality indications. The authors believe targeting the highest morbidity areas – while early and requiring more longevity data – are the correct innovations to seriously consider for underwriting adoption. Adoption could seamlessly impact data trends in prescription histories and medical claims.

During the preparation of this report, major advances in publicly available artificial intelligence tools have occurred and, perhaps, even gone mainstream. While not covered, this may be a fertile follow-up area for underwriting evaluations, especially to obtain data rapidly on a decentralized basis with the increasing ‘infowhelm’ in society.

Finally, the connectivity of insureds to the internet via their mobile and wearable devices is a tremendous opportunity for both protective value, and data gathering, and could benefit from industry incentives with labs and device companies for adoption – much like Google ‘hooked’ the public with free email and GPS directional apps.

Members are welcome to contact the authors for more input and questions, and we thank the SOA for this first opportunity to identify underwriting innovations of importance over the coming decade.
Section 6: Acknowledgements

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