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A Value-Based Approach to Insurer Coverage and Reimbursement for Molecular Diagnostic Tests

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I. INTRODUCTION

Healthcare is a constantly evolving industry, especially with regards to how physicians and other health care providers test, diagnose, and treat patient conditions.[1] Precision medicine is not a new endeavor,[2] but in the wake of President Obama's 2015 State of the Union Address, the push for more specific tests, more immediate diagnoses, and more targeted treatment approaches have been reinvigorated.[3]

Often, insurers are the last to adapt to changes within health care testing, diagnostics, treatment, and reimbursement decisions because of a lack of clinical utility, or evidence of a test's medical benefit.[4] However, with the

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1. Becki Rupp, *Health Care Industry Evolution and Trends: Reflections from an Insurance Veteran Part 1*, THE BENEFITS GUIDE (Sept. 21, 2015), https://thebenefitsguide.com/health-care-industry-evolution-trends-reflections-insurance-veteran-part/ (describing the expansion of coverage, evolution of the payer and provider relationship, and a shift in customer focus as major developments in health care in the past five years).

2. John R. Christiansen, *The Precision Medicine Initiative: Background and Issues for Participating Healthcare Organizations*, 28 NO. 1 HEALTH L. 38, 38 (2015) (stating that precision medicine has impacted medicine for years, primarily in the diagnosis and treatment of cancer and cardiology conditions).

3. Press Release, National Institutes of Health, NIH Awards $55 Million to Build Million-person Precision Medicine Study (July 6, 2016), https://www.nih.gov/news-events/news-releases/nih-awards-55-million-build-million-person-precision-medicine-study (explaining that the PMI is a longitudinal research project focused on improving disease prevention and treatment based on individual differences. Collaborations between data and research support centers, participant technology centers, healthcare provider organizations, and biobanks are several vital components to the PMI).

4. Patricia A. Deverka & Jennifer C. Dreyfus, *Clinical Integration of Next Generation Sequencing: Coverage and Reimbursement Challenges*, 42 J.L., MED. & ETHICS 22, 22 (2014); Anya E.R. Prince, *Prevention For Those Who Can Pay: Insurance Reimbursement of Genetic-Based Preventative Interventions in the Liminal State Between Health and Disease,* 2 J.L. &

support and the push for a more "targeted" approach to health care, insurers should change their approach to coverage and reimbursement for innovative diagnostic tests, such as molecular diagnostics.[5] Insurers should also provide greater coverage and reimbursement for tests that carry greater clinical utility and adjust coverage and reimbursement rates incrementally based on the available research. This should occur regardless of the presence of signs, symptoms or Food and Drug Administration (FDA) approval.[6] This innovative change in insurance coverage would reduce health care costs and continue to incentivize personalized medicine initiatives.[7]

The Precision Medicine Initiative (PMI)[8] reignited a focus in developing prevention, diagnostic, and treatment approaches that are tailored to the individual.[9] The PMI is a government funded initiative that requires a million person volunteer research cohort who will provide a detailed medical history, blood samples, and personal information to better understand how to improve diagnosis and treatment of diseases.[10] One notable PMI incentive involves lowering overall healthcare costs through early detection, prevention, and greater efficiencies in care delivery.[11] Precision medicine uses molecular

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BIOSCIENCES 365, 373 (2015).

5. Deverka & Dreyfus, *supra* note 4, at 23 (referring to coverage as the services a payer will pay for and under what circumstances and reimbursement at "the level of payment"); BRUCE QUINN, COVERAGE AND REIMBURSEMENT FOR MOLECULAR DIAGNOSTICS: CURRENT ISSUES AND OPTIONS, 8 (2009) (ebook).

6. PERSONALIZED MED. COAL., THE CASE FOR PERSONALIZED MEDICINE 22–23 (2014), http://www.personalizedmedicinecoalition.org/Userfiles/PMCCorporate/file/pmc_case_for_personalized_medicine.pdf [hereinafter CASE FOR PM] (noting that the FDA takes a tiered approach to regulation of lab-developed tests, with riskier clinical decisions taking longer to approve).

7. *See generally* CASE FOR PM, *supra* note 6, at 27–29 (explaining the incentives of personalized medicine); Deverka & Dreyfus, *supra* note 4, at 27 (explaining that long-term payment stability will ensure sufficient investment in newer technologies).

8. Robert Pear, *Uncle Sam Wants You—Or at Least Your Genetic and Lifestyle Information,* N.Y. TIMES (July 23, 2016), http://www.nytimes.com/2016/07/24/us/politics/precision-medicine-initiative-volunteers.html?_r=1.

9. Sairamesh Jakka & Michael Rossbach, *An Economic Perspective on Personalized Medicine*, 7 HUGO J. 1, 1 (Apr. 19, 2013), https://thehugojournal.springeropen.com/articles/10.1186/1877-6566-7-1#Sec3; Christiansen, *supra* note 2, at 38–39.

10. Pear, *supra* note 8.

11. Jakka & Rossbach, *supra* note 9, at 1.

diagnostics to identify predisposition, diagnostic, prognostic, and predictive biomarkers.[12] Providers may use biomarkers for simple tests, such as pulse detection and blood pressure readings, or more complex tests, such as blood chemistry and tissue analyses.[13] As laboratory-measured biomarker uses develop, the relationship between biomarkers and the clinical or surrogate endpoints[14] will become more valid.[15]

This article argues that innovative, molecular diagnostic tests that carry greater clinical utility should be covered and reimbursed at greater rates and incrementally decreased as the clinical utility of the test decreases, regardless of the presence of signs or symptoms. The incentive to adopt this proposed change in reimbursement structure could reduce long-term insurance costs by preventing, mitigating, and treating expensive health conditions.

The article will first address how insurers currently operate at both the public and private levels, followed by a discussion on how coverage and reimbursement policies for genetic testing are formed. Then, an argument in favor of adopting a value-based approach to coverage and reimbursement policies for molecular diagnostic testing will be presented. The remainder of the article will address the incentives for insurers to adopt a value-based approach to policies regarding molecular diagnostic testing and the counterarguments for adopting a value-based approach to cover and reimburse molecular diagnostic tests.

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12. *See generally* Kyle Strimbu & Jorge A. Tavel, *What are Biomarkers?*, 5 CURR. OPIN. HIV AIDS 463 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078627/pdf/nihms259967.pdf (explaining that a biomarker is "any substance, structure, or process that can be measured in the body or its products and influence or predict the incidence and outcome of disease").

13. *Id.*

14. *Id.* (defining clinical endpoints as a reflection of how a subject in a clinical trial feels, functions or survives; and surrogate endpoints as a substitute for clinically meaningful endpoints, which are often used to reference biomarkers that consistently and accurately predict clinical outcomes).

15. *Id.* (explaining that in order for a biomarker to serve as a surrogate endpoint, it has to provide clinically relevant information).

II. THE CURRENT INSURER APPROACH

Coverage and reimbursement determinations are the product of a variety of factors, including historical guidance regarding genetic conditions, clinical utility of the test, and individual circumstances.[16] For instance, private payer plans categorize benefits and services, in addition to listing exclusions.[17] However, the Patient Protection and Affordable Care Act (ACA) implemented dramatic changes to the way policies now define coverage, and what is included within them.[18]

In response to the need to reduce healthcare costs, public insurers have moved toward payment models that drive improvements in health care quality and efficiency.[19] Alternative payment models (APMs) demonstrate the goal to increase quality of care by reimbursing providers based on the value of care provided.[20] If properly implemented, APMs may support the growth of personalized medicine, in addition to reducing the cost of health care.[21]

Historically, Medicaid covered some genetic testing, mainly for molecular diagnostic tests for cancer.[22] Medicare typically covers and reimburses services similar to those that private insurers cover.[23] Most recently, the Medicare payment system was revised in regards to clinical diagnostic

16. Prince, *supra* note 4, at 379 (listing organizations such as the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, the Health Resources and Services Administration, and the USPSTF).

17. QUINN, *supra* note 5, at 12.

18. CASE FOR PM, *supra* note 6, at 35; Prince, *supra* note 4, at 378–80 ("[P]rivate insurers must cover any prevention method that the USPSTF has reviewed and recommended . . . CMS holds discretion as to which USPSTF recommendations are included in coverage.").

19. CASE FOR PM, *supra* note 6, at 27–28.

20. *Id*. at 28 (explaining that APMs can increase quality in health care by encouraging physicians to adopt targeted therapies based on an individual's genetics).

21. *Id*. at 27.

22. Prince, *supra* note 4, at 372.

23. *Id.* at 371 ("Medicare covers services that are 'reasonable and necessary for the diagnosis or treatment of illness or injury' . . . excluding coverage for tests 'performed in the absence of signs, symptoms, complaints, or personal history of disease or injury.'").

laboratory tests (CDLTs).[24] These revisions included the FDA's approval of advanced diagnostic laboratory tests (ADLTs) and changes to the payment structure to equal the weighted median determined for the test based on private payer rates.[25] Additionally, Medicare created a pilot program called the Medicare Molecular Diagnostic Services Program (MolDx).[26] This program evaluates genetic tests and identifies and establishes coverage and reimbursement policies for molecular diagnostic testing.[27]

Private insurers rely on Medicare for guidance on reimbursement policies and cost,[28] and oppose investing in personalized coverage.[29] This reliance is due to a lack of clear evidence showing measurable medical benefits or clinical utility.[30] Similar to public insurers, private insurers generally take a reactionary approach[31] when it comes to coverage and reimbursement policies.[32] When private insurers decide whether to cover genetic testing, the

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24. Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System, 81 Fed. Reg. 41,036, 41,036 (June 23, 2016) (to be codified at 42 C.F.R. pt. 414) (defining CDLTs as tests that are created and sold by a single laboratory, have been cleared or approved by the FDA, and are paid under the Clinical Laboratory Fee Schedule (CLFS) prior to January 1, 2017).

25. *Id.* at 41,098 (defining ADLTs as a subcategory of CDLTs covered under Medicare Part B, is created and sold by a single laboratory, and the test either (1) analyzes multiple biomarkers to yield a patient-specific result; (2) has been approved by the FDA; or (3) meets similar criteria established by the Secretary).

26. Sarah H. Beachy et al., Board on Health Sciences Policy Institute of Medicine, *Roundtable on Translating Genomic-Based Research to Health*, in ASSESSING GENOMIC SEQUENCING INFO. FOR HEALTH CARE DECISION MAKING: WORKSHOP SUMMARY 55 (2014).

27. Regence, *Genetic and Molecular Diagnostics - Single Gene or Mutation Testing*, MEDICARE ADVANTAGE POL'Y MANUAL 2 (Sept. 15, 2016), http://blue.regence.com/medicare/gt/m-gt20.pdf (indicating that MolDx has not been adopted by all contractors in all states and confirming that molecular diagnostic tests continue to exclude testing in the absence of signs or symptoms).

28. Prince, *supra* note 4, at 371–72; Deverka & Dreyfus, *supra* note 4, at 27.

29. Jakka & Rossbach, *supra* note 9, at 3.

30. Prince, *supra* note 4, at 373 (explaining that the gap between evidence of clinical use of genetic tests and evidence for insurance coverage can be explained by the lack of evidence regarding cost-effectiveness of the genetic tests because the tests screen for rare diseases that are not prevalent in society).

31. CASE FOR PM, *supra* note 6, at 9 (explaining that insurers frame coverage and reimbursement policies to address when an individual has received a diagnosis rather than focusing on preventing the disease in the first place); Jakka & Rossbach, *supra* note 9, at 1.

32. Jakka & Rossbach, *supra* note 9, at 2; Prince, *supra* note 4, at 366–70 (explaining that insurers typically provide coverage for treatment more often than for prevention and leave no

determining factor is often whether the proposed genetic test or intervention is medically necessary.[33] Moreover, private insurers determine coverage and reimbursement policies for molecular diagnostics through a wide range of assessment procedures.[34] The practice of using multiple assessments creates substantial inconsistencies in the insurer's reimbursement decisions and often leads to test manufacturers' or insured persons' inability to predict what molecular diagnostic tests would be covered and reimbursed.[35] Even when a private insurer provides coverage for genetic testing, the coverage determinations are often difficult to find within the policy.[36] The insured person could be faced with difficulties when he or she is interested in a particular genetic test, but is unsure of whether the private insurer provides coverage for the test.[37] This could deter the individual from receiving genetic testing at all or could require a drawn out process of further review by the private insurer to adjudicate the claim.[38] Moreover, private insurers explicitly exclude a genetic test if it is for informational purposes in the absence of a family history of a condition, or in the instance a minor is tested for an adult onset condition.[39]

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room for asymptomatic individuals to seek coverage for preventative interventions).

33. Prince, *supra* note 4, at 369–70, 375 (noting additional considerations for whether a private insurer decides to cover genetic testing include the clinical validity and clinical utility of the test and if the test would have a direct effect on treatment, or if it would prevent diseases in high-risk patient. Clinical validity is whether the test and the clinical outcome correlate. Clinical utility occurs when the information from the test provides greater incentives when compared with current management without testing); *see also* Deverka & Dreyfus, *supra* note 4, at 36 (noting recent success that some prenatal NGS tests have been assessed to be medically necessary).

34. Ildar Akhmetov & Rostyslav V. Bubnov, *Assessing value of innovative molecular diagnostic tests in the concept of predictive, preventative, and personalized medicine*, 6 THE EPMA J. 1, 7 (2015) ("[S]ome payers use up to seven assessment frameworks to reason their reimbursement decisions . . . while others give preference to only one or two.").

35. *Id*.

36. Prince, *supra* note 4, at 372.

37. DEP'T HEALTH & HUM. SERVS., SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH, & SOC'Y (SACGHS), COVERAGE AND REIMBURSEMENT OF GENETIC TESTS AND SERVICES 17 (Feb. 2006), http://osp.od.nih.gov/sites/default/files/CR_report.pdf.

38. *Id.*

39. Prince, *supra* note 4, at 372.

Innovations drive health care in a direction that makes "precise" care more cost-effective for both the consumer and the insurer.[40] However, inconsistent standards used to evaluate molecular diagnostic tests create an obstacle to implementing precision care.[41] Organizations, such as the Institute of Medicine (IOM) and the Centers for Disease Control (CDC), published guidance for minimizing inconsistent standards and effectively demonstrating a test's clinical utility.[42] The Evaluation of Genomic Applications in Practice and Prevention (EGAPP) also recently recommended several changes to the evaluation of genomic technology.[43] The EGAPP focuses on expediting the review process for genetic testing by triaging tests and eliminating those that are not currently reviewable, using and updating existing reviews, and using decision models to assess potential clinical utility when direct evidence is unavailable.[44] The current glacial pace at which genomic technology is evaluated[45] slows payer decisions about coverage and reimbursement for genetic testing because of a lack of the required evidence of clinical utility.[46] Therefore, the EGAPP recommendations would likely accelerate evaluations and provide payers with the necessary evidence of clinical utility in order to begin expanding

40. *See, e.g.*, *Id*. at 463 (explaining when LTDs lack FDA approval, CMS has been advised to consider Medicare reimbursement for genetic testing when strong evidence of improved health outcomes exists).

41. PERSONALIZED MED. COAL., THE FUTURE OF COVERAGE AND PAYMENT FOR PERSONALIZED MEDICINE DIAGNOSTICS 15, http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/pmc_the_future_coverage_payment_personalized_medicine_diagnostics.pdf (last visited Dec. 15, 2016) [hereinafter FUTURE OF COVERAGE].

42. David R. Parkinson et al., *Evidence of Clinical Utility: An Unmet Need in Molecular Diagnostics for Patients with Cancer*, 20 CLINICAL CANCER RES. 1428, 1432 (2014).

43. Deverka & Dreyfus, *supra* note 4, at 25.

44. *Id.* (explaining that payers have a 'de factor role of enforcing clinical utility standards' because no regulatory body has specific oversight).

45. ADVAMEDDX, A POLICY PRIMER ON DIAGNOSTICS 18 (2011), https://dx.advamed.org/sites/dx.advamed.org/files/resource/advameddx-policy-primer-on-diagnostics-june-2011.pdf (explaining that evaluation of new tests require direct evidence of patient outcomes, code assignment, and rate-setting that often disregards the test value, all of which slow down patient access to new diagnostic tests).

46. Deverka & Dreyfus, *supra* note 4, at 25 (noting that the EGAPP has issued only nine recommendations over the course of seven years).

coverage and reimbursement for more innovative and personalized health care.[47]

III. COVERAGE AND REIMBURSEMENT POLICIES FOR MOLECULAR DIAGNOSTIC TESTING: A VALUE-BASED APPROACH

Conceptually, payers favor personalized medicine because of the potential cost-effectiveness in treating an individual based on his or her molecular makeup.[48] Molecular diagnostic testing will likely require insurers to adopt an entirely new coverage and reimbursement paradigm.[49] Under the current cost-based reimbursement approach, the value and cost saving potential molecular diagnostics provide are not usually reflected in the reimbursement and deter investment in personalized medicine.[50] Payers should develop a value-based approach to coverage and reimbursement for molecular diagnostics[51] because precision medicine pushes for more targeted health care approaches[52] and access to clinical utility evidence for genetic testing is what drives payer coverage and reimbursement policies.[53] By shifting to a value-based insurance design (V-BID), providers would be encouraged to use high-value services, leading to a more targeted approach to health care.[54]

Medicare has begun adjusting the coverage and reimbursement system by implementing the MolDx Program in a number of jurisdictions to facilitate

47. Parkinson, *supra* note 42, at 1442 (noting that if payers prioritize tests of potentially high clinical utility and improve reimbursement for genetic tests, it would incentive private investors to continue investing in future genetic test development).

48. Deverka & Dreyfus, *supra* note 4, at 22.

49. *Id.* at 28 (suggesting molecular diagnostics be reimbursed based on the value of the test); W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419, 460 (2015).

50. Deverka & Dreyfus, *supra* note 4, at 28.

51. *Id.* (supporting that payers develop an approach that is at least "predictable, objective and appropriate third party reimbursement payment structure that will improve patient outcomes, support patient access, and ensure continued investment and innovation").

52. Christiansen, *supra* note 2, at 38.

53. Deverka & Dreyfus, *supra* note 4, at 25; FUTURE OF COVERAGE, *supra* note 41, at 16.

54. SUZANNE F. DELBANCO ET AL., URBAN INSTITUTE, VALUE-BASED INSURANCE DESIGN 3 (2016), http://www.urban.org/sites/default/files/01_value-based_insurance_design.pdf.

the incorporation of molecular diagnostic tests.[55] Due to the unique nature of molecular diagnostic tests, the MolDx Program strives to create consistency in coverage and pricing for these tests.[56] Additionally, BlueCross BlueShield (BCBS) Association's TEC has developed a similar assessment program for molecular diagnostics.[57] Programs like MolDx and BCBS Association's TEC help ameliorate barriers to the insurer's decision to cover and reimburse for molecular diagnostic testing by standardizing the process for evaluating molecular diagnostics.[58]

Medicare and BCBS have made efforts to standardize how molecular diagnostic tests are evaluated in order to make coverage and reimbursement decisions. However, both public and private insurers continue to face the issue of deciding which molecular diagnostic tests to cover. For molecular diagnostic testing, all insurers should provide greater levels of coverage and reimbursement for molecular diagnostics that have high clinical utility and provide lower levels of coverage and reimbursement for testing that has lower clinical utility, regardless of the presence of signs or symptoms.[59] Additionally, the ACA implements a value-based approach by offering value-based exchange plan options.[60] Further, the FDA takes a value-based approach when regulating lab-developed tests (LDTs)[61] by requiring that

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55. PALMETTO GBA, MOLECULAR DIAGNOSTIC PROGRAM (MOLDX) 1 (2016), http://palmettogba.com/Palmetto/moldx.Nsf/files/MolDX_Manual.pdf/$File/MolDX_Manual.pdf [hereinafter MOLDX WHITE PAPER].

56. *Id*.

57. Deverka & Dreyfus, *supra* note 4, at 28.

58. *Id*.

59. Wylie Burke et al., *Recommendations for Returning Genomic Incidental Findings? We Need to Talk!*, 15 GENETICS IN MED. (SPECIAL REPORT) 854, 856 (2013) ("It is an established precept of public health that screening should be instituted only when there is compelling evidence that it improves health outcomes in asymptomatic people.").

60. Magaly Olivero, *Obamacare: Which 'Metal' Tier is Right for You?*, U.S. NEWS & WORLD REP. (Nov. 14, 2014, 8:00 AM), http://health.usnews.com/health-news/health-insurance/articles/2014/11/14/obamacare-which-metal-tier-is-right-for-you (indicating that more comprehensive coverage accompanied the more expensive plans).

61. Gail H. Javitt & Katherine Strong Carner, *Regulation of the Next Generation Sequencing*, 42 J.L., MED. & ETHICS 9, 14 (2014) (explaining that LDTs are laboratory-assembled tests that use a patient specimen, issue a lab report with the test results, and are both

"tests linked to riskier clinical decisions" need longer to approve.[62] Value, in this instance, emphasizes the perceived or anticipated value the consumer seeks to gain, rather than the actual cost of the plan or test.[63] Typically, the most important factors in a public or private insurer's decision to cover molecular diagnostics are the "rate of payer adoption" and "the time that is needed for [the diagnostic] approval."[64] Regardless of the questionable authority the FDA has over LDT regulation,[65] the FDA favors tests with prognostic indicators over tests that influence clinical decisions.[66]

However, it is important to remember that insured persons are also are affected by insurer coverage and reimbursement decisions. Therefore, potential emotional and psychological responses of insured persons to coverage decisions should be considered when deciding whether to cover molecular diagnostic testing. With the PMI's goal of recruiting one million individuals as a volunteer group, what happens to an individual after learning about the presence of a genetic predisposition?[67] If an individual's insurance does not offer (or provides insufficient) coverage and reimbursement for follow-up treatment, individuals could be psychologically harmed.[68]

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developed and approved by the lab); Deverka & Dreyfus, *supra* note 4, at 24.

62. CASE FOR PM, *supra* note 6, at 22–23; Jakka & Rossbach, *supra* note 9, at 5 ("There is a trend towards outcome- and value-based pricing and reimbursement models in many countries and this greatly increases the financial value of P4 medicine, and . . . the incentives to invest in it."); *see* Price, *supra* note 49, at 458 (explaining how medical devices are classified by risk by the FDA).

63. Mark Haller & Avynash Gersappe, *Value-based Pricing: Putting the Customer at the Center of Price*, PWC (2014), https://www.pwc.com/us/en/advisory/customer/assets/value-based-pricing.pdf.

64. Jakka & Rossbach, *supra* note 9, at 5.

65. Javitt & Carner, *supra* note 61, at 14.

66. Jakka & Rossbach, *supra* note 9, at 5 (explaining that the FDA would request premarket approval for tests that directly influence clinical decisions, compared to prognostic indicator tests that may only need a 510 (k) approval).

67. National Institutes of Health, *Precision Medicine Initiative Cohort Program - Frequently Asked Questions*, https://www.nih.gov/precision-medicine-initiative-cohort-program/precision-medicine-initiative-cohort-program-frequently-asked-questions (last updated Oct. 7, 2016).

68. Prince, *supra* note 4, at 373–74 (explaining the psychological side effects of receiving genetic testing results including anxiety and depression).

Additionally, if the treatments are expensive and are not covered, low-income individuals could be disproportionally affected after learning of the presence of a genetic predisposition.[69] This potential for psychosocial harms may deter individuals from participating in the PMI, leading to restrictions in innovative healthcare diagnosis and treatment efforts.[70]

IV. INCENTIVES FOR INSURERS TO COVER AND REIMBURSE MOLECULAR DIAGNOSTICS

Both public and private insurer decisions are driven by incentives to reduce healthcare costs, especially as annual costs have grown significantly.[71] Cost savings related to molecular diagnostic testing is also often delayed.[72] However, the incentives accompanying the wait go far beyond the financial gains insurers could realize[73] if universal adoption of a value-based approach to coverage and reimbursement of molecular diagnostic testing occurs.[74]

Insurers are typically risk averse and coverage for newer tests are also considered risky.[75] One of the biggest risks is the cost-effectiveness of the tests compared with the benefits.[76] Often, it is difficult to identify which

69. Price, *supra* note 49, at 462 n.215.

70. *E.g.*, Prince, *supra* note 4, at 374 (noting that a person may have to resort to insurance appeals or litigation in order to secure coverage for preventative medical interventions after genetic testing).

71. NAT'L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, DIV. CMTY. HEALTH, UNDERSTANDING VALUE-BASED INSURANCE DESIGN 1 (2015), https://www.cdc.gov/nccdphp/dch/pdfs/value_based_ins_design.pdf.

72. A. MARK FENDRICK & SEEMA S. SONNAD, VALUE-BASED INSURANCE DESIGN FOR DIAGNOSTICS, DEVICES, & PROCS. 24 (2012), http://vbidcenter.org/wp-content/uploads/2014/08/V-BID-and-Devices-InHealth.pdf (explaining that targeted services may increase short-term costs, but would likely lead to lower aggregate costs. It is the fear of the insurer that the benefits occur too far "downstream" to offset the initial costs of utilizing a targeted approach).

73. Akhmetov & Bubnov, *supra* note 34, at 2 (noting the economic impact of molecular diagnostic testing for variants that guide the initial dosing of warfarin have the potential to provide $1.1 billion in annual savings and prevent 17,000 strokes).

74. DELBANCO, *supra* note 54, at 3 (indicating benefits, such as improving customer health through beneficial, high-value services, reducing wasteful spending, and aligning patient needs with provider initiatives to improve the quality of care and make it more affordable).

75. Jakka & Rossbach, *supra* note 9, at 3.

76. *Id.*

genetic tests will save money, as savings are often not known until after the test has been on the market for an extended period of time.[77] Additionally, no structure currently exists for insurers to assess the cost savings from prognostic and preventative diagnostic testing.[78]

However valid insurer risk adversity may be, the incentives and benefits for insurers to cover and reimburse molecular diagnostic testing far outweigh the costs.[79] A prevention approach, compared to a reaction approach, would likely lead to short-term costs,[80] but would lead to long-term savings by utilizing a targeted approach for diagnosis, testing, and treatment.[81] For instance, if a preventable disease were diagnosed at an individual's young age, cost savings would likely be realized in adulthood.[82]

Several benefits of using biomarkers when treating individuals include decreased hospital admission costs and reduced prescription costs.[83] Adverse drug reactions are costly to treat,[84] but biomarkers can enhance drug-related safety in patients who may have otherwise experienced an adverse reaction.[85] For example, clinical trials for a new medicinal treatment may have been found to be a success if twenty-five percent of participants benefitted from

77. *Id.* at 2–3.

78. *Id.* at 3.

79. *See generally* CASE FOR PM, *supra* note 6, at 27–29 (explaining the incentives of personalized medicine).

80. Jakka & Rossbach, *supra* note 9, at 3 (noting that cost savings are often not known until after the test has been on the market for an extended period of time which make it difficult to identify which tests and technologies will truly save costs).

81. CASE FOR PM, *supra* note 6, at 8, 29.

82. *Id.* at 8.

83. *Id.* at 12–13; *see, e.g.*, Debra Hughes, *Consortium Antidepressant Guidelines Represent a 'Template for Psychiatric Precision Medicine,'* MONTHLY PRESCRIBING REFERENCE (Sept. 2016) (illustrating the potential benefits precision medicine could provide to patients by recognizing inherent genetic variations and recommending physicians consider alternative medications based on an individual's genetic make-up).

84. Elizabeth Burke et al., *Pharmacogenetic Testing: Application in Mental Health Prescribing*, 22 J. AM. PSYCHIATRIC NURSES ASS'N 185, 185 (2016) ("Every year in the United States, the cost of treating medication-related adverse events reaches $76 billion.").

85. CASE FOR PM, *supra* note 6, at 12; Jakka & Rossbach, *supra* note 9, at 2 ("30-40% of patients receive ineffective drugs; which can lead to adverse reactions that are costly to treat.").

the treatment.[86] However, if a person's genetic make-up was considered, treatment for the other seventy-five percent of patients could be tailored to his or her genetic profile, leading to greater efficacy of medicinal treatment.[87] Furthermore, pharmaceutical companies have implemented biomarker development in clinical trials after recognizing the value of personalized medicine and molecular diagnostic testing.[88]

Additionally, trial and error dosing and prescription of medications could be minimized, or even eliminated, with an increased use of biomarkers in treatment.[89] Compliance with medication would then likely increase with the use of genetic diagnostics.[90] Often, individuals do not comply with their medication because of the side effects.[91] For others, their body metabolizes the drug too rapidly for the medication to work.[92] Molecular diagnostics can improve a physician's understanding of individual genetic variations, which would help mitigate side effects through individualized dosing and would also help avoid prescribing medications that would be ineffective. Thus, potential cost savings for insurers serve as an incentive to use genetic testing and offer coverage and reimbursement policies that reflect those cost savings.[93]

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86. Antoinette F. Konski, *Personalized Medicine: Insights Into Current Legal Issues*, Personalized Medicine Bulletin (Sept. 18, 2016), https://www.personalizedmedicine bulletin.com/2016/09/18/personalized-medicine-insights-into-current-legal-issues/.

87. *Id.*

88. Akhmetov & Bubnov, *supra* note 34, at 3 (explaining that fifty percent of clinical trials conducted by pharmaceutical companies have focused on biomarker development).

89. CASE FOR PM, *supra* note 6, at 13.

90. *Id.* at 14 (regarding treatment for hypercholesterolemia, "patients with a genetic diagnosis have shown more than 86% adherence to treatment program after two years, compared to 38% prior to testing").

91. *Id.*

92. *Id.* at 13.

93. *See, e.g.*, Konski, *supra* note 86 ("By way of example, it has been projected that the frequency of chemotherapy could be decreased by thirty-four percent in women with breast cancer if they all received genetic testing prior to treatment.").

V. CONCLUSION

A value-based approach to healthcare is not a novel concept. However, the application of a value-based approach to coverage and reimbursement policies for molecular diagnostics is a newer concept that should be explored. Although insurer costs may increase due to a change in reimbursement policies, the overall health insurance market may see cost savings as chronic diseases are prevented and the current problem of paying for prevention is minimized.[94] Coverage and reimbursement policies must adapt to the ever-changing needs of the healthcare industry, especially in light of the expanded use of molecular diagnostics and the reinvigorated emphasis on personalized precision medicine.

94. Prince, *supra* note 4, at 390; *see also* Akhmetov & Bubnov, *supra* note 34, at 3 (stating that molecular diagnostic testing have contributed to 30–50 percent reductions in hospital and outpatient charges); *see, e.g.* THE KAISER FAMILY FOUND., *Snapshots: How Changes in Medical Technology Affect Health Care Costs* (Mar. 2, 2007), http://kff.org/health-costs/issue-brief/snapshots-how-changes-in-medical-technology-affect/ (highlighting that new vaccines may be costly at first, but often lead to cost savings if the vaccine results in fewer people seeking expensive treatment).