

REPORT 6 OF THE COUNCIL ON MEDICAL SERVICE (A-18)
Integrating Precision Medicine into Alternative Payment Models
(Reference Committee G)

EXECUTIVE SUMMARY

Genetic/genomic discoveries and precision medicine innovations are occurring simultaneously with payment and delivery reforms that require health care services to demonstrate value as a prerequisite for payment and coverage. The sustained push to contain health care costs has led to increased interest in alternative payment models (APMs) that incentivize high-quality, cost-effective care. Examples of well-known APMs include accountable care organizations, bundled payments, and patient-centered medical homes.

Precision medicine is a tailored approach to health care that accounts for individual variability in the genes, environment, and lifestyle of each person. It has the potential to revolutionize the diagnosis and treatment of disease and may ultimately help address rising health care costs by streamlining clinical decision-making, reducing unnecessary treatments and hospitalizations, tailoring treatments, reducing late-stage diagnoses, and improving outcomes over time.

APMs have the capacity to incentivize use of care protocols, clinical pathways and other decision support tools. However, the structure of APMs often requires cost savings within a specific window of time that may not account for improved outcomes downstream. The Council initiated this report to explore how APMs can support and integrate precision medicine services to provide high-quality, high-value health care. The Council's recommendations encourage APMs to consider the value of precision medicine and to integrate precision medicine approaches into patient care where appropriate and when recommended by national medical specialty societies.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 6-A-18

Subject: Integrating Precision Medicine into Alternative Payment Models

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Referred to: Reference Committee G
(Theodore A. Calianos, II, MD, Chair)

1 This report, initiated by the Council, explores how alternative payment models (APMs) can support
2 and integrate genetic/genomic precision medicine services with the end goal of providing high-
3 quality, high-value health care. Previous Council reports have discussed physician-focused APMs
4 (Report 9-A-16) and barriers that interfere with the shift to these value-based payment models
5 (Report 10-A-17). Policy developed via the I-17 Joint Report of the Councils on Science and
6 Public Health and Medical Service is intended to facilitate more consistent payment and coverage
7 for evidence-based genetic/genomic precision medicine services.

8
9 This report discusses APMs and precision medicine; describes clinical pathways and decision
10 support tools; provides examples of APMs that incorporate precision medicine approaches;
11 discusses AMA activity; summarizes relevant AMA policy; and presents policy recommendations.

12 BACKGROUND

13
14
15 Precision medicine, which is a tailored approach to health care that accounts for individual
16 variability in the genes, environment and lifestyle of each person, has the potential to revolutionize
17 diagnosis and treatment of disease and, in doing so, improve health outcomes downstream. It has
18 the potential to more accurately diagnose disease, predict individual susceptibility to disease, detect
19 the onset of disease at earlier stages, and reduce invasive procedures and no longer necessary
20 screenings and treatments. Physicians already practice precision medicine by diagnosing and
21 treating each patient according to his or her unique symptoms, history, and preferences. However,
22 significant advances in technology—including the development of large-scale biological databases,
23 powerful methods for characterizing patients (eg, proteomics, metabolomics, genomics, cellular
24 assays, and mobile health technologies), and computational tools for analyzing large sets of data—
25 have vastly expanded the ability to apply precision medicine principles to patient care.

26
27 Accelerated rates of genetic/genomic discoveries and clinical innovations are occurring
28 simultaneously with payment and delivery reforms including the proliferation of APMs driven by
29 the push for cost-containment strategies and value-based purchasing. Driven by the Affordable
30 Care Act (ACA) and Medicare Access and Chip Reauthorization Act (MACRA), the Centers for
31 Medicare & Medicaid Services (CMS) has developed and implemented a number of initiatives to
32 test APMs.

33
34 New health care payment and delivery models focus on value and require that health care services
35 demonstrate their value to patients and the health care system as a prerequisite for payment and
36 coverage. The sustained push to contain health care costs has led to increased interest in APMs that
37 incentivize high-quality, cost-effective care. Examples of well-known APMs include accountable

1 care organizations (ACOs), bundled payments, and patient-centered medical homes (PCMHs).
 2 APMs have the capacity to create incentives for the use of care protocols, clinical pathways, and
 3 shared decision-making. However, such tools should reflect advances in precision medicine and
 4 support continued scientific innovation so that “one-size-fits-all protocols” are not universally
 5 imposed when evidence-based targeted treatments may be more cost-effective in the long term.

6
 7 Precision medicine holds the potential to improve patient care and may ultimately help address
 8 rising health care costs overall by streamlining clinical decision-making, reducing unnecessary
 9 treatments and hospitalizations, tailoring treatments, reducing late-stage diagnoses, and improving
 10 outcomes over time. For example, genotype testing of patients initiating warfarin treatment has
 11 been found to reduce hospitalizations for bleeding or thromboembolism.¹ Another study estimated
 12 that there would be substantial cost savings (\$604 million) if patients with metastatic colorectal
 13 cancer were screened for the KRAS gene prior to beginning treatment.² A retrospective analysis of
 14 precision medicine outcomes in patients with advanced cancer found improved progression-free
 15 survival and lower charges per week for patients who received genomic testing and targeted
 16 therapy.³ Over time, it is anticipated that genetic/genomic services will become more affordable
 17 and thus potentially produce greater cost savings. Payment and coverage for genetic/genomic
 18 services, which was addressed in the I-17 Joint Report, continues to be a barrier to patient access to
 19 precision medicine. While some genetic/genomic tests and therapeutics are covered by insurers,
 20 many others are not, and there is substantial variability among public and private insurers with
 21 regard to payment and coverage and prior authorization requirements. Coverage may also vary
 22 based on the intended use of genetic/genomic testing.

23
 24 The market shift from a fee-for-service (FFS) to a value-based model should support and
 25 encourage the adoption of evidence-based genetic/genomic precision medicine services. However,
 26 it is a challenge to design new payment models that aim to improve care for whole populations
 27 while implementing precision medicine that is aimed at identifying the correct diagnosis and
 28 treatment plan for an individual patient. Stakeholders must engage in ongoing discussions to
 29 identify areas where APMs and precision medicine may work together and support one another. If
 30 properly designed and incentivized, together APMs and precision medicine have the capacity to
 31 yield better care, better health, and lower costs over the long term.

32
 33 **POTENTIAL IMPACT OF APMS ON PRECISION MEDICINE**

34
 35 Precision medicine represents life-altering opportunities and potential. However, policymakers
 36 must be diligent to appropriately weigh the balance between quality and cost-savings and, in
 37 particular, short term cost-savings. The drive to make genetic/genomic medicine available may be
 38 stifled when providers are assessed or penalized for spending, as they are in APMs. Such
 39 assessment of providers based on spending may be particularly problematic when that spending
 40 yields improvements that cannot be considered in a specific or small window of time.⁴

41
 42 A recent MedPAC report denotes a potential issue with the structure of many APMs being that the
 43 paradigm of cost savings in a specific period of time may be appropriate for some services and
 44 procedures that have remained unchanged over the course of many years; however, such a structure
 45 may not be appropriate for new tests and technologies, especially those that might improve patient
 46 quality of life over the course of many years.⁵ For example, it may be challenging to align a
 47 payment system, such as a bundled payment APM, with the appropriate quality measures. While
 48 the use of precision medicine could improve a patient’s quality of life or prevent downstream
 49 disease recurrence, it is difficult to identify and promote quality measures that capture the value of
 50 such interventions within a specified window. Policymakers must acknowledge such challenges of

1 implementing precision medicine within the context of APMs so as to realize the potential of
 2 innovative technologies to improve care quality, value, and patient satisfaction.

3
 4 As medical knowledge of the genome continues to evolve and grow, the number of options and
 5 tools to assist providers in diagnosis and treatment is rapidly expanding. While tens of thousands of
 6 genetic tests are currently available,⁶ there is widespread variability in the costs and insurer
 7 coverage of these tests and clinicians may have a difficult time determining the right test for a
 8 given patient. For example, oncology clinical practice guidelines currently recommend more than
 9 30 tumor biomarkers across all cancers to support appropriate treatment and decision-making with
 10 the list of potential biomarkers growing and changing in response to the rapid pace of clinical
 11 research.⁷ Genetic tests range from testing for a specific alteration and a specific gene to testing
 12 large genetic panels on many hundreds of genes at the same time.⁸ Though guidelines from the
 13 National Comprehensive Cancer Network and other professional groups help direct physicians to
 14 the best genetic tests for a given patient, physicians need the decision support to help determine
 15 which mutations to consider for a specific tumor type and what genetic tests are most appropriate
 16 for a given patient. Studies have suggested that many physicians report being inadequately
 17 prepared to use genetic/genomic information for patient care,⁹ while others remain unsure that
 18 genomic information is clinically useful.^{10,11} Education and awareness are needed for successful
 19 implementation of genetic/genomic precision medicine, and tools used by APMs may be able to
 20 help address some of the knowledge gaps.

21
 22 **CLINICAL PATHWAYS AND DECISION SUPPORT TOOLS**

23
 24 Many APMs already create incentives to use care protocols, clinical pathways, and other decision
 25 support tools in treatment decision-making. Pathways act as a decision support tool for physicians
 26 to know the right genetic test to use for each patient based on the nature of the patient's disease.¹²
 27 The pathways then recommend treatments based on the test results. At times these pathways
 28 receive prior authorization from payers, having the effect of expediting the process of getting the
 29 test and treatment to the patient. Yet many providers can have difficulty using the decision support
 30 resources necessary to assess the value of precision medicine when confronted with high upfront
 31 costs of new technologies.

32
 33 Often clinical pathways produce a single instance of savings after use. However, because pathways
 34 are generally developed based on the broader population, requirements to adhere to clinical
 35 pathways may have the effect of constraining the ability of providers and patient to identify and
 36 choose the patient's best available treatment options. Therefore, one-size-fits-all pathways and
 37 adherence requirements may result in missed opportunities to tailor treatment based on individual
 38 patient genetics, environment, and lifestyle choices.

39
 40 Stakeholders are attempting to combat the issue of one-size-fits-all pathways by using data
 41 registries that expand the evidence base of available therapies. The use of data registries and rapid
 42 learning systems can extract clinically relevant data and apply the data to practice guidelines in
 43 real-time. One example of an adjustable pathway model is the Department of Veterans Affairs
 44 (VA) Point-of-Care Precision Oncology Program (POCOP). The POCOP uses electronic health
 45 records (EHRs) and real-time data sharing to integrate knowledge from external sources about
 46 molecular medicine in cancer with experience and information of other veterans in the program
 47 including genomic information from a patient's tumor and history with prior therapies.¹³
 48 Ultimately, the POCOP could guard against simply using short-term lower cost pathways and serve
 49 as a model of rapid data-sharing, creating an evidence base that is continuously updated and can
 50 inform treatment decisions at the point of care.¹⁴

1 Similarly, the American Society of Clinical Oncology (ASCO) is developing a rapid learning
2 system by building a cloud-based, big data, health IT platform called CancerLinQ.¹⁵ CancerLinQ
3 extracts data from EHRs and other data sources and employs data analytics to generate knowledge
4 that is available at the point of care to oncologists and patients. The primary objective of the
5 learning system is to provide real-time feedback to physicians to enable them to deliver
6 personalized insights at the point of care and accelerate new clinical hypotheses and pathways by
7 uncovering patterns in patient and tumor characteristics, therapies, and outcomes. As precision
8 medicine evolves and we gain insight on the role of genetic and other variation in patient response
9 to treatment, clinical pathways and other decision support tools will need to keep pace.

10 11 INCOPORATING PRECISION MEDICINE INTO APMS TO IMPROVE DIAGNOSIS

12
13 A current barrier in the health care delivery and payment system is a lack of payment for some key
14 aspects of the work associated with obtaining an accurate diagnosis. Current payment structures
15 often do not pay for consultation with other physicians, and patients often face delays in access to
16 care, particularly specialists, which can lead to exacerbations in symptoms and disease progression
17 before a diagnosis is established and a treatment plan is developed. Furthermore, often significant
18 amounts of time are dedicated to ruling out diagnoses rather than establishing an accurate
19 diagnosis. This issue of the diagnostic odyssey is driven in part by the structure of FFS in which
20 payments are made for conducting tests rather than paying for the process of determining what tests
21 to order.

22
23 To overcome this barrier, APMs should be encouraged to leverage technology to support the goals
24 of the APM and help physicians improve patient engagement, collaboration, diagnosis, treatment
25 planning, and quality. APMs have the capacity to support more accurate diagnoses and tailored
26 treatment plans, and precision medicine can play an important role in realizing this potential. Not
27 only can APMs support collaborative efforts between various health professionals such as
28 pathologists, radiologists, and others, but also, APMs, with the help of clinical pathways and
29 guidelines, can pay for targeted genetic and genomic tests that support faster and more accurate
30 diagnoses and the development of an individualized treatment plan. It is important to note that
31 genetic/genomic testing provides clinical information beyond diagnostics, including prognosis and
32 therapeutic tailoring. APMs should support new approaches to care delivery, and precision
33 medicine is an important component of achieving more accurate diagnoses.

34 35 EXAMPLES OF APMS IMPLEMENTING PRECISION MEDICINE

36 37 *The Radiation Oncology Alternative Payment Model (RO-APM)*

38
39 Though the role of precision medicine across health care settings and payment models is still
40 evolving, oncology care illustrates how an APM can help support precision medicine. Specifically,
41 the American Society for Radiation Oncology is developing the RO-APM, which would
42 incentivize the appropriate use of cancer treatments that result in the highest quality of care and
43 best patient outcomes. The RO-APM holds physicians accountable for the spending related to the
44 condition and applies to major disease sites treated with radiation therapy, creating an episode-
45 based payment that begins with clinical treatment planning and concludes 90 days after the last
46 radiation treatment. Throughout the episode, clinicians must adhere to nationally accepted clinical
47 treatment guidelines and other quality improvement requirements.

48
49 With the use of genetic/genomic precision medicine, providers can optimize radiation therapy
50 based on a patient's tumor profile. Its use can shape dosage to minimize side effects and spare
51 healthy tissue. A recent study conducted at the University of North Carolina found that

1 approximately 20 percent of radiation therapy patients experienced an unplanned hospital
 2 admission within 90 days of their treatment.¹⁶ Precision medicine can yield better, more targeted
 3 treatment planning to lower the risk of post-radiation therapy toxicities and avoid the need for
 4 toxicity-related inpatient visits. An APM can support enhanced patient monitoring and better
 5 management of patient care and result in fewer inpatient visits, ultimately decreasing the average
 6 cost of care per radiation therapy patient.

7
 8 *Patient-Centered Oncology Payment*

9
 10 The ASCO developed the Patient-Centered Oncology Payment (PCOP) model to improve the
 11 quality and affordability of cancer care. The model pays practices for services that are not currently
 12 billable, including non-face-to-face visits and consultation with other specialists, and imparts
 13 practices with the flexibility to tailor services to unique patient needs, which results in the delivery
 14 of high-quality, individualized services. The PCOP system is designed to provide supplemental,
 15 non-visit-based payments to practices to support accurate diagnosis, treatment planning, and care
 16 management. Using PCOP, practices would bill for new patient treatment planning, care
 17 management, active monitoring, and participation in clinical trials. In return for PCOP paying
 18 adequately for patient services at the outset, practices agree to adhere to appropriate use criteria and
 19 other accepted standards of care. Furthermore, practices and payers agree to a robust performance
 20 measurement system, so payers are assured that oncology practices are accepting accountability for
 21 spending and agreeing to standards of care while focusing on care approaches that have the
 22 demonstrated ability to lower costs without harming quality.¹⁷

23
 24 *Private Insurer Incorporating Precision Medicine into Value-Based Care*

25
 26 Harvard Pilgrim Health Care is an example of a private insurer that has taken steps to incorporate
 27 precision medicine into a value-based care model. In February 2018, Harvard Pilgrim entered into
 28 a contract with the test developer Illumina to broaden eligibility of noninvasive, prenatal genetic
 29 testing to pregnant women under age 35 (average risk pregnancies). While the insurer anticipates
 30 that savings on other prenatal screenings will offset the costs of the next generation sequencing
 31 tests, Illumina has agreed to pay for cost overages. A two-year study will help determine whether
 32 expanded availability of noninvasive prenatal genetic testing will affect spending and demonstrate
 33 clinical value to patients.¹⁸

34
 35 **AMA ACTIVITY**

36
 37 The AMA continues to work to aid physicians in the implementation of APMs and other
 38 components of MACRA. The AMA has conducted educational activities including webinars and
 39 regional conferences for physicians and staff and continues these activities. Recent AMA advocacy
 40 activity has called for improvements in the methodologies behind APMs to reduce barriers and
 41 enable more physicians to participate. The AMA has made extensive comments on all MACRA
 42 proposed and final rules and has successfully advocated for a number of changes, including the
 43 modification of the definition of financial risk.

44
 45 AMA advocacy efforts are also focused on the Physician-Focused Payment Model Technical
 46 Advisory Committee (PTAC) and Physician-Focused Payment Models (PFPMs). The AMA
 47 attends and makes public comments at meetings of the PTAC, submits comments on its draft
 48 documents and stakeholder proposals, and works with specialty societies developing PFPM
 49 proposals to help address challenges they face in APM design. To that end, the AMA has convened
 50 APM workshops to bring together many of the leading physicians who are working on PFPM
 51 proposals to discuss potential solutions to these issues.

1 The AMA is also engaged in ongoing advocacy related to genetic/genomic precision medicine,
2 including oversight of laboratory-developed tests, and implementation of the Protecting Access to
3 Medicare Act which significantly revised the Medicare payment system for laboratory tests,
4 including genetic tests.

5
6 *Health IT and Digital Health*

7
8 Significant improvements in EHRs and other health IT capabilities are critically needed for
9 precision medicine to reach its potential under the new payment models. Robust and interoperable
10 health IT systems must be able to access and display longitudinal health data from each patient
11 regardless of where the data are stored. EHRs hold biological, behavioral and environmental data;
12 however, impediments to accessing and securely exchanging data across health care systems must
13 be overcome. The AMA actively promotes EHRs that can provide clinical decision support and use
14 genetic/genomic data to provide clinically meaningful information to physicians. The AMA's
15 Integrated Health Model Initiative supports a continuous learning environment to enable
16 interoperable technology solutions and care models that evolve based on real-world use and
17 feedback.

18
19 Beyond EHRs, the AMA is committed to influencing the evolution of health IT and digital health,
20 both of which are integral to the implementation of precision medicine. The AMA provides
21 leadership on digital solutions involving telemedicine and telehealth, mobile health, wearables, and
22 remote monitoring. Using the expertise of physicians and input from partners on the leading edge
23 of health technology, the AMA has developed resources, toolkits and training to help physicians
24 evaluate and optimally use newly available technology for improved care.

25
26 Additionally, the AMA continues to educate physicians about the clinical uses of genetic/genomic
27 services. To assist physicians encountering new precision medicine technologies, the AMA has
28 partnered with Scripps Translational Science Institute and The Jackson Laboratory to develop
29 "Precision Medicine for Your Practice," a series of online continuing medical education modules
30 covering topics such as expanded carrier screening in prenatal care, prenatal cell-free DNA
31 screening, somatic cancer panel testing, large scale sequencing as a diagnostic tool, and
32 pharmacogenomics.¹⁹ The AMA has partnered with the NIH *All of Us* Research Program, a soon-
33 to-be launched precision medicine initiative to study one million or more Americans.^{20, 21}
34 Furthermore, the AMA has conducted surveys to better understand physician awareness and
35 confidence with precision medicine practices. The AMA is also maintaining dialogue with other
36 key stakeholders through activities such as the National Academies of Science, Engineering and
37 Medicine Genomics Roundtable.²²

38
39 **RELEVANT AMA POLICY**

40
41 Policy H-385.913 created foundational policy to support the appropriate shift to physician-focused
42 APMs. Policy H-385.913 promulgated goals for physician-focused APMs, developed guidelines
43 for medical societies and physicians to begin identifying and developing APMs, and encouraged
44 CMS and private payers to support provision of assistance to physician practices implementing
45 APMs. The policy has been influential in related AMA advocacy thus far, which has included
46 submission of extensive comments on the MACRA proposed and final rules and responses to draft
47 documents from the PTAC and proposed models from Center for Medicare & Medicaid
48 Innovation. The AMA has a key role in helping physicians develop and participate in APMs.

49
50 Building on Policy H-385.913, Policy H-385.908 offers a set of guidelines to address the barriers
51 that interfere with the shift to value-based payment. Such barriers to the development and

1 implementation of APMs include limitations of existing health IT capabilities, resource use
2 measures, and resource use challenges including risk adjustment, attribution, and performance
3 target-setting.

4
5 The AMA has extensive policy related to physician-led payment reform models. AMA policy is
6 committed to promoting physician-led payment reform programs that serve as models for others
7 working to improve patient care and lower costs (Policy D-385.963). Policy H-390.844 emphasizes
8 the importance of physician leadership and accountability to deliver high quality and high value to
9 patients. In transitioning from the sustainable growth rate (SGR), the AMA advocates for providing
10 opportunities for physicians to determine payment models that work best for their patients, their
11 practices, and their regions (Policy H-390.844). Policy D-390.953 directs the AMA to advocate
12 with CMS and Congress for APMs developed in concert with specialty and state medical
13 organizations. Policy H-450.931 recognizes that physicians will need assistance transitioning to
14 APMs.

15
16 Policy H-390.849 directs the AMA to advocate for the adoption of physician payment reforms that
17 promote improved patient access to high-quality and cost-effective care and that such reforms be
18 designed with input from the physician community. It calls for reformed payment rates that are
19 sufficient to maintain a sustainable medical practice and that payment reform implementation
20 should be undertaken within a reasonable timeframe and with adequate assistance.

21
22 Policy D-185.980 established foundational policy on payment and coverage for genetic/genomic
23 precision medicine. The policy encourages payers to adopt processes and methodologies for
24 determining coverage and payment for genetic/genomic precision medicine that: promote
25 transparency and clarity; involve multidisciplinary stakeholders; describe the evidence being
26 considered; provide opportunities for comment and review as well as meaningful reconsiderations;
27 and incorporate value assessments that consider the value of genetic/genomic tests and therapeutics
28 to patients, families and society as a whole, including the impact on quality of life and survival.
29 Policy D-185.980 also encourages the development of a comprehensive payment strategy that
30 facilitates more consistent coverage of genetic/genomic tests and therapeutics that have clinical
31 impact, and also encourages national medical specialty societies to develop clinical practice
32 guidelines incorporating precision medicine approaches.

33
34 Policy H-410.948 provides guidance on the development of clinical pathways and supports the
35 development of transparent, collaboratively constructed clinical pathways that are implemented in
36 ways that promote administrative efficiencies for both providers and payers; promote access to
37 evidence-based care for patients; recognize medical variability among patients and individual
38 patient autonomy; promote access to clinical trials; and are continuously updated to reflect the
39 rapid development of new scientific knowledge. Additionally, the AMA has significant and
40 comprehensive policy on health IT. Policy H-450.933 encourages efforts to develop and fund
41 clinical data registries; supports flexibility in the development and implementation of clinical data
42 registries; encourages physicians to participate in clinical data registries; and advocate for and
43 support initiatives that minimize the costs of physician participation in clinical data registries.

44 45 DISCUSSION

46
47 With MACRA taking effect and precision medicine gaining traction in clinical practice, the
48 Council believes that physicians need to lead the development and integration of these two
49 promising innovations. It is important that the payment and delivery reform movement recognizes
50 the incremental value of precision medicine, especially as more evidence of its effectiveness
51 becomes available. With the emergence of APMs and the drive to value, the AMA is poised to be a

1 leader in addressing unnecessary care costs and realizing the benefits of APMs, and one of the most
2 valuable ways to maximize value may be through precision medicine, particularly for certain
3 specialties.

4
5 The Council believes that clinical pathways provide an opportunity to confront the tension between
6 achieving cost-savings targets and providing better patient care and improving outcomes and
7 recognizes the utility of data registries. To that end, AMA policy on clinical pathways (Policy
8 H-410.948) and data registries (Policy H-450.933) is recommended for reaffirmation. To further
9 ensure that clinical pathways are successful, the Council recommends affirming that they should be
10 developed by clinical experts, including national medical specialty societies, and be leveraged by
11 or integrated into EHRs for decision support, unified documentation, and automation of
12 communication with payers for authorization.

13
14 Because expert-driven, evidence-based clinical pathways can help physicians identify
15 genetic/genomic tests and services for patients, the Council recommends encouraging APMs to
16 incorporate them as appropriate and as recommended by national medical specialty societies. The
17 Council further believes that appeal mechanisms should be available to patients and physicians
18 when national medical specialty society-recommended pathways are rejected. The Council also
19 recognizes the potential impact of rapid learning systems on precision medicine and APMs, and
20 recommends supporting transparent and accessible rapid learning systems with the ability to extract
21 clinically meaningful information and use it to modify clinical practice guidelines and pathways in
22 real-time.

23
24 For many providers, especially those participating in APMs, it is challenging to use the resources
25 necessary to assess the full clinical and economic value of precision medicine when confronted
26 with high up front cost of new technologies, particularly when the use of new tests or therapeutics
27 may negatively affect a provider's cost-savings targets. Accordingly, the Council recommends that
28 the AMA support assessment within new payment and delivery models of the value of evidence-
29 based precision medicine tests and therapeutics to patients, families and the health care system,
30 including the impact on patient experience, disease progression, quality of life and survival.

31
32 The Council firmly believes that the APM focus on lowering costs must not have the unintended
33 effect of discouraging adoption and use of innovative tests and therapeutics that, though more
34 expensive in the short-term, have the potential to deliver better long-term outcomes for patients.
35 Accordingly, the Council recommends that the AMA encourage APMs to integrate precision
36 medicine approaches, where appropriate, to improve the diagnostic process and personalize patient
37 care.

38
39 Finally, the Council recognizes that a key challenge to integrating precision medicine into new
40 payment models is that APMs are generally structured around cost savings within a specified
41 window of time and may not account for improved outcomes downstream. Therefore, the Council
42 recommends that the AMA encourage APMs to consider measuring patient outcomes and quality
43 improvements over time to allow for the use of precision medicine tests and therapeutics that have
44 clinical value.

1 RECOMMENDATIONS

2
3 The Council on Medical Service recommends that the following be adopted and that the remainder
4 of the report be filed:

- 5
6 1. That our American Medical Association (AMA) reaffirm Policy H-410.948 supporting the
7 development of transparent, collaboratively constructed clinical pathways that promote
8 administrative efficiencies and access to evidence-based care, recognize variability among
9 patients and individual patient autonomy, promote access to clinical trials, and are
10 continuously updated to reflect new scientific knowledge. (Reaffirm HOD Policy)
11
12 2. That our AMA reaffirm Policy H-450.933 encouraging efforts to develop and fund clinical
13 data registries, and supporting flexibility in the development and implementation of
14 clinical data registries. (Reaffirm HOD Policy)
15
16 3. That our AMA reaffirm Policy H-185.980, which encourages public and private payers to
17 adopt a series of processes and methodologies for determining coverage and payment for
18 genetic/genomic precision medicine. (Reaffirm HOD Policy)
19
20 4. That our AMA affirm that clinical pathways should be developed by clinical experts,
21 including national medical specialty societies, and should be leveraged by or integrated
22 into electronic health records for decision support, seamless documentation, and
23 automation of communication with payers for authorization. (New HOD Policy)
24
25 5. That our AMA encourage alternative payment models (APMs) to incorporate evidence-
26 based clinical pathways as appropriate and as recommended by national medical specialty
27 societies. (New HOD Policy)
28
29 6. That our AMA support transparent and accessible rapid learning systems with the ability to
30 extract clinically meaningful information and use it to modify clinical practice guidelines
31 and pathways in real-time. (New HOD Policy)
32
33 7. That our AMA support assessment within new payment and delivery models of the value
34 of evidence-based precision medicine tests and therapeutics to patients, families and the
35 health care system, including the impact on patient experience, disease progression, quality
36 of life and survival. (New HOD Policy)
37
38 8. That our AMA encourage APMs to integrate precision medicine approaches, where
39 appropriate, to improve the diagnostic process and personalize patient care. (New HOD
40 Policy)
41
42 9. That our AMA encourage APMs to measure patient outcomes and quality improvements
43 over time to allow for the use of precision medicine tests and therapeutics that have clinical
44 value. (New HOD Policy)

Fiscal Note: Less than \$500.

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- ¹³ *Supra* note 4.
- ¹⁴ *Id.*
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