Medicare Policy at the Crossroads

Addressing Artificial Intelligence and Software

August 2023

CapView STRATEGIES | AdvaMed
Advanced Medical Technology Association

"The greatest opportunity offered by AI is not reducing errors or workloads, or even curing cancer: it is the opportunity to restore the precious and time-honored connection and trust—the human touch—between patients and doctors. Not only would we have more time to come together, enabling far deeper communication and compassion, but also we would be able to revamp how we select and train doctors."

Eric Topol, MD
Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again

"Ultimately, we're all trying to improve care and quality of life for patients. Using data, we can scale innovations to help people far beyond our walls."

Dr. John D. Halamka, President, Mayo Clinic Platform
Q&A: Mayo Clinic Platform (RamaOnHealthcare)

"The time is now for CMS to harness its leadership role in health care to build a comprehensive strategy on AI/software in Medicare and across the health care system."

AdvaMed / CapView Strategies

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Executive Summary

Medicare beneficiaries stand to gain greatly from the ethical development and use of artificial intelligence (AI) and software solutions that improve the diagnosis and treatment of illness and disability, promote healthy behaviors, and support population health management. Advancements in quality, health outcomes, and health system savings can be achieved with access to these innovations.

As noted in the previous CapView/AdvaMed report, "Modernizing Medicare Coverage of Digital Health Technologies,"[1] the Centers for Medicare & Medicaid Services (CMS) has the regulatory flexibility to improve access by covering and paying for digital health technologies—including AI/software—within Medicare's benefit categories and under current law. However, the Agency has not yet fully implemented this flexibility in coverage and payment pathways. As the largest payer in health care, CMS should harness both its regulatory flexibility and marketplace power to address access, equity, and ethical issues for AI/software innovations in Medicare, and across the health care system. This report outlines a comprehensive strategy for moving forward.

Looking across Medicare's payment systems, policies are identified where CMS has already made changes to address AI/software solutions. Examples include paying for autonomous AI that can diagnose diabetic retinopathy as a physician service and acknowledging an AI solution that accelerates the time to treatment in a hospital for patients experiencing stroke. Targeted recommendations to address challenges in coverage and payment across Traditional Medicare, Medicare Advantage, and alternative payment models are also presented.

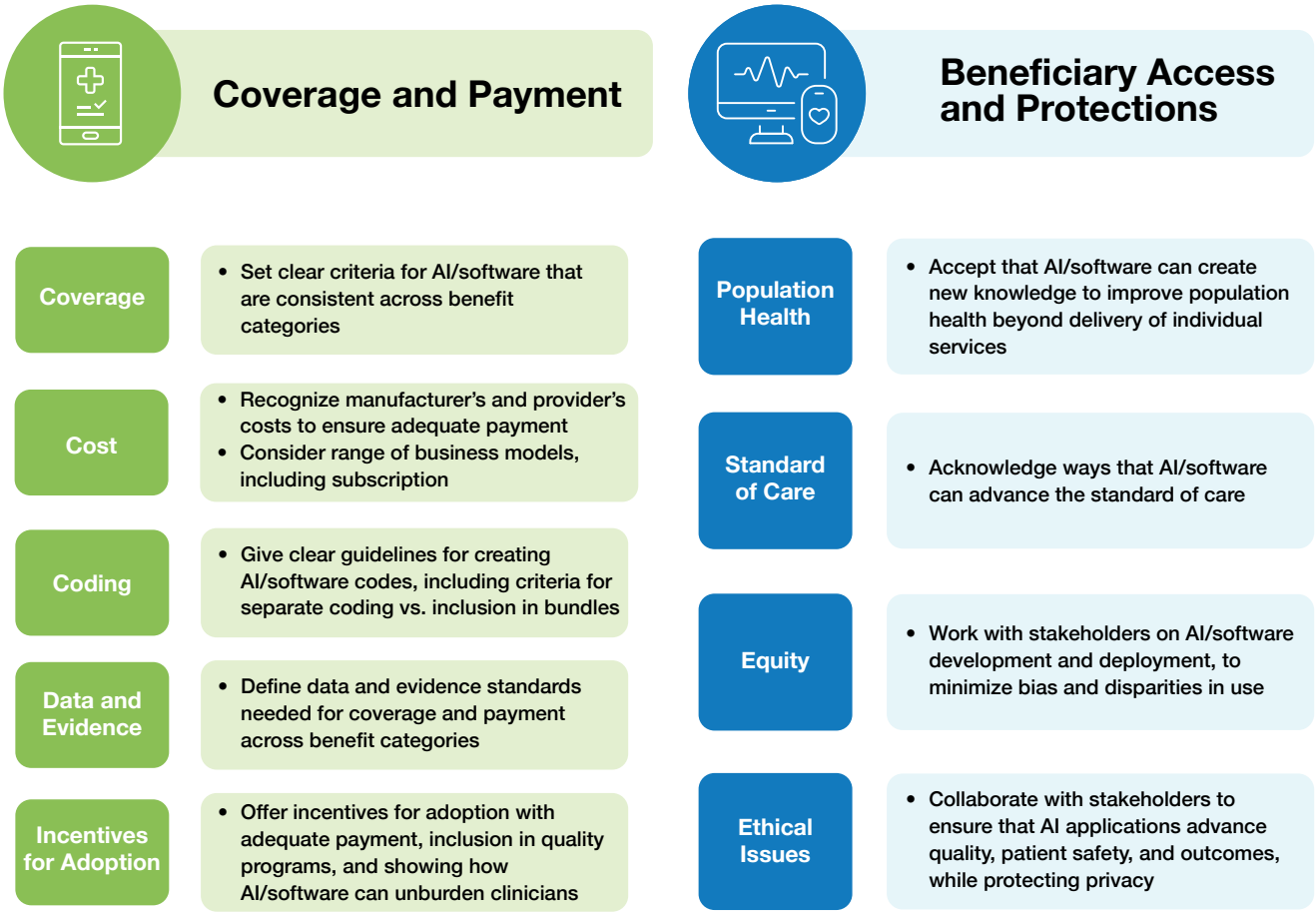
COMPREHENSIVE MEDICARE AI/SOFTWARE STRATEGY

CMS' recent policy decisions and the report's targeted recommendations offer some promising solutions for AI/software coverage and payment in Medicare. Yet, interviews with experts from manufacturing companies, a detailed regulatory analysis, and a review of the literature found that Medicare's policies lack a comprehensive, systematic methodology for recognizing the unique attributes and costs of these technologies. A set of core considerations (**Exhibit 1**) are identified to guide CMS in implementing a more holistic approach both in its coverage and payment decisions, and in Medicare's development of access and beneficiary protection guardrails.

This report recommends a Comprehensive Medicare AI/software Strategy (**Exhibit 2**) that CMS should implement to advance the Agency's approach on coverage and payment policies for these innovative and transformative technologies. The comprehensive strategy outlines steps for the Agency to:

- **Strengthen CMS Leadership.** As a first step, CMS should appoint a Chief AI Officer, charged with expanding and elevating CMS' leadership role on AI/software issues and improving

Exhibit 1. Core Considerations for AI/software in Medicare



Source: CapView Strategies/AdvaMed Analysis

collaboration within the government and across private sector stakeholders, including patients, providers, payers, and manufacturers.

- **Take Action on Key Policy Issues.** The CMS Chief AI Officer should lead the comprehensive strategy and assure key foundational steps are taken for the ethical, equitable, and privacy-protecting deployment of innovative AI/software technologies. The specific steps include:
  - **Implementing targeted recommendations.** To build on the regulatory flexibility available for the coverage and payment of AI/software solutions, CMS should implement the 25 recommendations outlined in Part II of this report. The targeted recommendations address current issues and challenges specific to payment systems in Medicare. This step would assure an accurate and consistent foundation to addressing coverage, cost, and data issues for AI/software technologies across Medicare's payment systems.
  - **Addressing core considerations.** CMS should evolve its policies to account for the unique features, functions, and costs associated with the use and development of AI/software. These core considerations should guide decisions on coverage and payment as well as those focusing on beneficiary access and protections. The core considerations should apply not only to Medicare, and each of the program's benefit categories, but also to the role of AI/software in the evolving health care system, focusing on personalized,

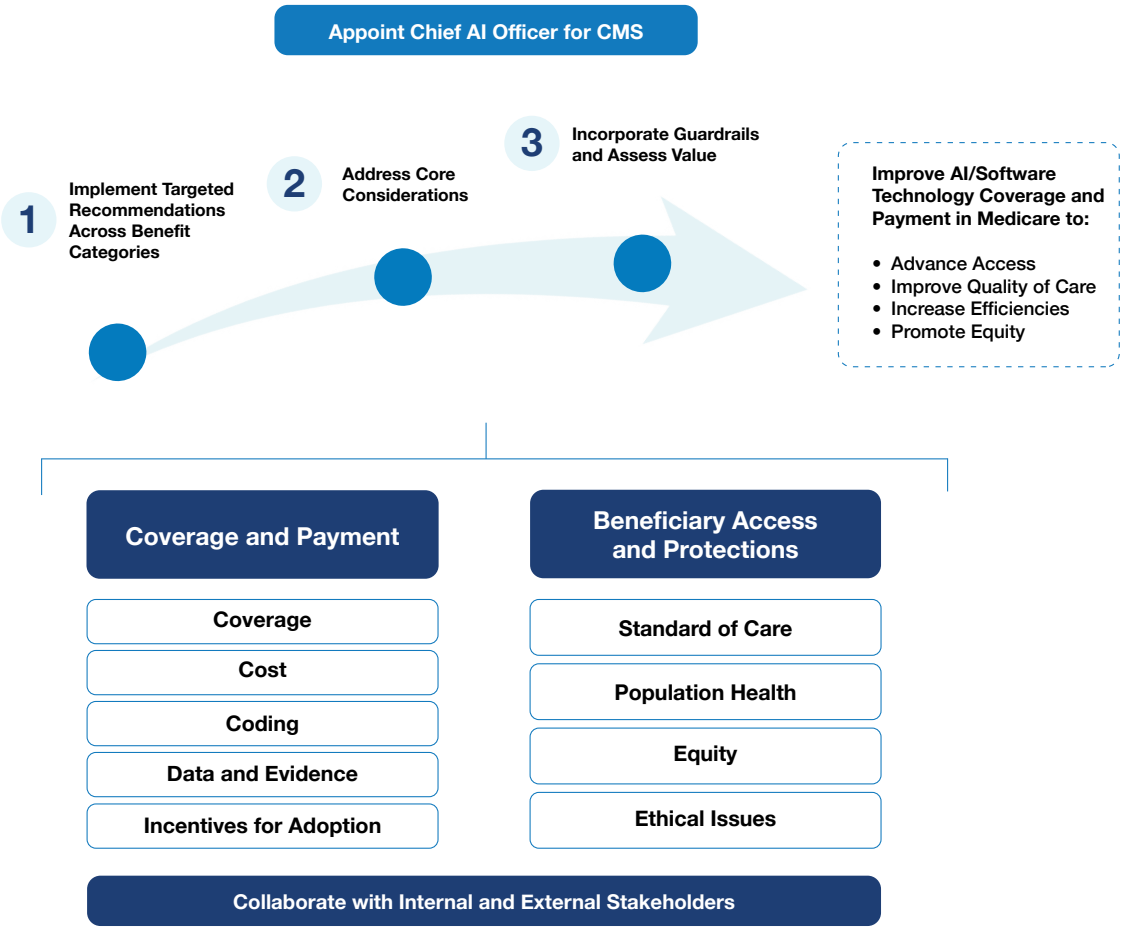
community-oriented solutions, and value-based care initiatives.

- **Incorporating guardrails and assessing value.** CMS must ensure that AI/software technologies used in the care of patients advance quality of care and health outcomes. AI/software solutions should be appropriate, ethical, and non-biased, while protecting the privacy of beneficiary information. CMS should work with stakeholders and other federal agencies to identify specific value drivers and guardrails, such as data and evidence needs, transparency requirements, appropriate monitoring tools over time, and links to quality measures. Guardrails will be essential to maximizing the potential of these technologies, while also establishing appropriate beneficiary protections.

- **Leverage Medicare's Marketplace Power.** As CMS' policies evolve to better incorporate AI/software into Medicare, this new comprehensive strategy creates a system-wide approach to coverage and payment across settings. It strengthens current payment policies, promotes collaboration on key issues, and ensures beneficiaries have access to new technologies. By collaborating with stakeholders, the strategy also addresses the considerations key to the ethical development and use of new, innovative AI/software in health care.

The time is now for CMS to take a leadership role on access, coverage and payment, and equity issues regarding AI/software in Medicare, and across the health care sector.

Exhibit 2. Comprehensive Medicare AI/software Strategy



Source: CapView Strategies/AdvaMed Analysis

Introduction

CapView collaborated with AdvaMed to develop this new report on improving coverage and payment for AI/software in Medicare. This work builds on the analysis and recommendations from an earlier collaboration.[2] As described in the first report, CMS has the regulatory flexibility to incorporate digital health technologies—including AI/software innovations—into its payment pathways as the statutory parameters for Medicare's benefit categories accommodate evidence-based, digital health solutions. This second report updates the previous analysis with a specific focus on AI/software.

The first report defined digital health technologies as tools that facilitate the electronic or mobile collection and analysis of data used to inform health care decision-making or behaviors, and to support the provision of care on a remote basis. This new report narrows the focus to AI/software solutions that use data and analytics, powered by advanced computing science, to improve patient health outcomes and health care delivery. These innovations support a range of activities from collecting and organizing data to facilitating clinical decision-making. They involve advanced algorithms and machine learning (ML), which is the use of statistical and mathematical modeling "to automatically learn and improve" on specific tasks without further programming.[3] Using these tools, AI/software can assist in making a diagnosis, recommend a course of treatment, improve care delivery, or fully automate a care process.

CHANGING POLICY LANDSCAPE

Since the first report, the number of AI/software solutions has grown, as have research and policy activities investigating the implications of AI/software in health care. The issues and recommendations developed by the National Academy of Medicine (NAM), Government Accountability Office (GAO), and the American Medical Association (AMA) have helped to shape the thinking and analysis in this report. Additionally, AdvaMed recently released "A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystem," which will help medical technology companies and other stakeholders to assess the value of AI/software used in a health care service.[4]

Innovations that leverage AI/software in health care are occurring within a broader context where societal concerns have arisen about AI leading to negative impacts in employment, housing, and other areas of daily life also lead to caution about the impact of AI in health care.[5] For example, in a recent poll, more than half of the respondents expressed discomfort with their provider relying on AI for their medical care and worried that it could affect their relationships with providers, although many also saw benefits, such as a reduction in clinical errors and decreased bias.[6]

The Medicare program has a responsibility to address these concerns as it works to ensure that beneficiaries benefit from AI/software solutions. It also has the tools to do so. As discussed further below, these tools include the rigorous review of most new products by the Food and Drug

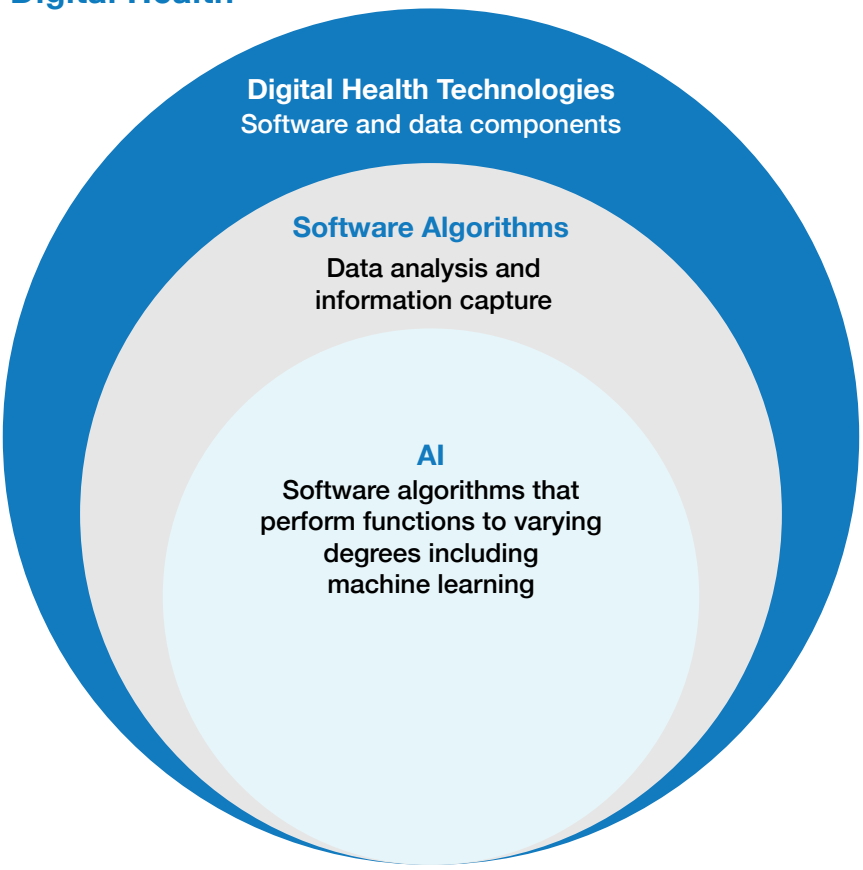
Administration (FDA) as well as the application of Medicare's own evidence-based processes to determine whether a technology is reasonable and medically necessary for the Medicare population. As the largest payer, Medicare also has the responsibility to take a leadership role and collaborate with both policymakers and stakeholders to realize the benefits of AI/software for health care and address equity, privacy, and ethical concerns for patients and providers.

RECENT PROGRESS AND CHALLENGES

This report looks across the Medicare program to identify where CMS has already made changes to cover and pay for AI/software solutions and highlight where challenges exist and improvements are necessary. CMS generally considers only the costs of using a technology in providing care when it sets payment rates and not the value of the technology to Medicare beneficiaries or the Medicare program. The value of the technologies, however, is much larger and may include avoiding acute exacerbations of chronic conditions, earlier diagnosis, or improvements in quality of life. Better recognition of the value of innovative technologies could enhance their adoption and advancement as well as their potential to improve health outcomes for Medicare beneficiaries.

Recent Medicare advances in coverage and payment include paying for autonomous AI that can diagnose diabetic retinopathy as a physician service and acknowledging an AI solution that accelerates the time to treatment for patients experiencing stroke in the hospital setting. While these individual decisions are promising, the analysis found that a more comprehensive approach would improve coverage and payment in Medicare. For example, the lack of clarity on coverage and payment as well as the need for a more systematic approach to Medicare coverage for digital therapeutics has limited access to new, FDA approved therapies for Medicare beneficiaries. These gaps have also had serious implications, including bankruptcy, for innovator companies.[7] While such therapeutics can be used in the home by beneficiaries, a clear path has not been established for

Exhibit 3. AI/software are Core Components of Digital Health



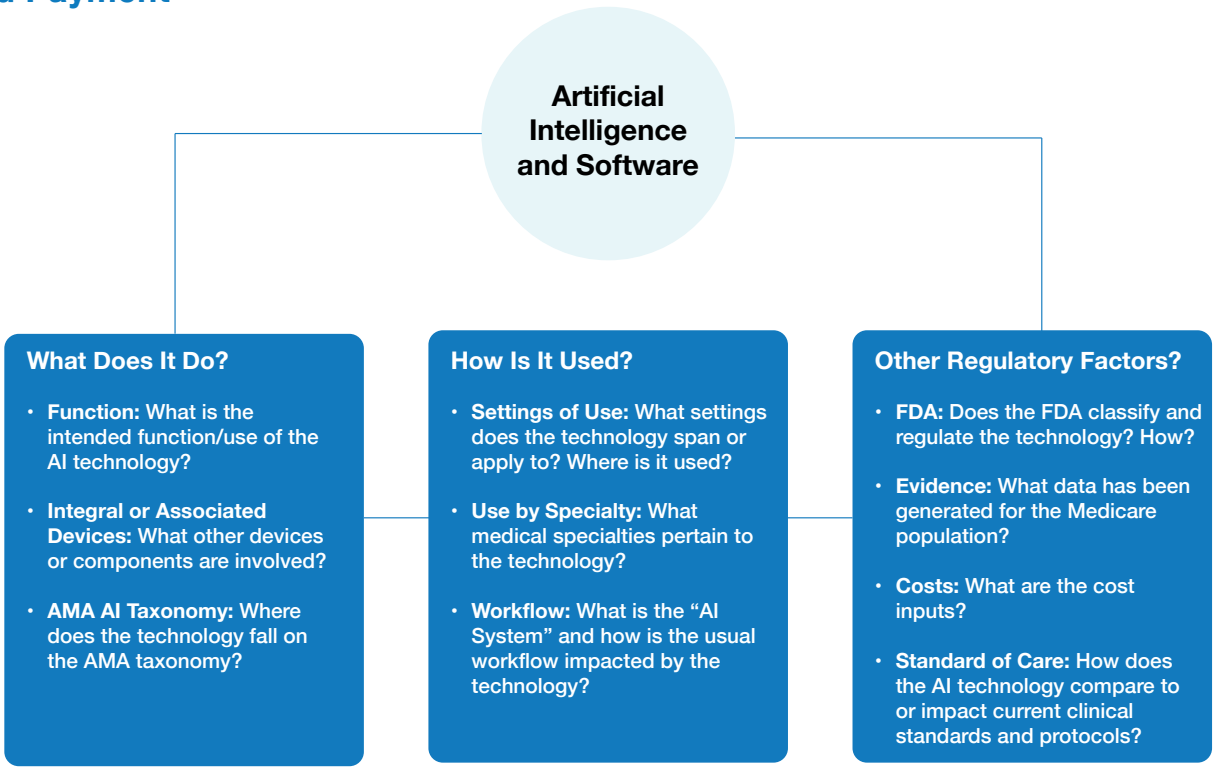
Source: CapView Strategies/AdvaMed Analysis

coverage and payment in Medicare either as home equipment under durable medical equipment (DME) or as a distinct service under the physician fee schedule. This not only creates a chilling effect on innovation as companies have no clear path to coverage, but also a potentially negative impact on quality of care across the health care system for patients who could have benefited from access to the technology.

PERSPECTIVES FROM MANUFACTURING COMPANIES

As a key component of this analysis, manufacturing company experts participated in interviews regarding the clinical roles, unique attributes, and costs of AI/software in health care—and particularly in Medicare. **Exhibit 4** presents the discussion questions posed to participants. The focused discussions provided information on the trends in AI/software development, described the range of established and emerging technologies currently available in health care, and identified manufacturers' plans for future development of AI/software solutions. New trends in AI/software innovations were described for use across the health care continuum, as well as potential modifications of current technologies to meet new health care needs. Key challenges and opportunities for improving access and coverage and payment policies in Medicare were identified. These discussions informed the core considerations presented in Part I and the regulatory analysis and recommendations in Part II.

Exhibit 4. Attributes of AI/software in the Context of Medicare Coverage and Payment



Source: CapView Strategies/AdvaMed Analysis

REPORT ORGANIZATION AND METHODOLOGY

Part I of this report outlines a comprehensive policy strategy for CMS to address the unique attributes of AI/software technologies in Medicare's coverage and payment policies. Part II presents targeted recommendations for CMS to consider across Traditional Medicare, Medicare Advantage (MA), and alternative payment models (APMs). The recommendations address gaps and challenges where Medicare's coverage and payment policies do not fully recognize the clinical potential and costs of AI/software (**Exhibit 5**).

Exhibit 5. Report Methodology

This report is based on a systematic review of the current issues that Medicare patients, providers, digital health technology (AI/software) manufacturers, and CMS face in the uptake and diffusion of new technologies. A combination of primary and secondary research informed the analysis and recommendations in the report, including:

Company Interviews. CapView conducted interviews with 28 AdvaMed member companies engaged in developing innovative AI/software solutions across the health care system. These interviews helped to identify issues and challenges in the current Medicare coverage and payment pathways included in Parts I and II of this report. The interviews were also important in identifying core considerations for the development of a new, comprehensive Medicare strategy for the coverage and payment of AI/software. Companies interviewed represented the following types of AI/software technologies:

- Monitoring Equipment
- Therapeutic Devices
- Diagnostic Equipment
- Decision/Risk Analysis
- Laboratory Services
- Personal Wellness Products
- Medical Supplies
- Software Applications
- Pharmaceuticals

Literature Review. CapView analyzed peer-reviewed journal articles and policy papers on digital health coverage and payment issues in health care.

Regulatory Review. CapView conducted a detailed regulatory analysis of Medicare's benefit categories and payment policies, including recent regulatory changes pertaining to AI/software.

Part I. Advancing a Comprehensive Medicare AI/Software Strategy

The use of AI/software in health care delivery can support personalized treatments, predictive analytics, improved diagnostics and screening, medication management, and more accurate procedures. AI/software tools include everything from image-assisted diagnosis and surgical robots to smart health monitoring systems and technology-assisted implanted medical devices. Moving forward, innovative technologies will continue to leverage the power of data and analytics to improve health outcomes and health care delivery. However, while AI/software are creating better and more targeted health care delivery, the Medicare program has yet to fully account for these important innovations in its coverage and payment policies, despite incremental changes in coverage and payment decisions in recent years.

This means that Medicare beneficiaries may not benefit fully from new technologies and solutions. And, to the extent that Medicaid and private payers follow Medicare coverage policies, individuals with other forms of insurance coverage could also be impacted. Coverage and payment for AI/software solutions in Medicare must consider the value and the costs of these technologies to ensure sustainable and predictable financial incentives for both clinicians and AI/software creators. The value of these solutions can include improved efficiencies in care delivery, care outcomes, and quality of care that go beyond the input costs of a service. Part I presents:

- AI/software in Health Care
- Federal Role and Emerging Policy Issues
- Unique Attributes and Costs of AI/software
- Core Considerations
- Value and Guardrails
- Comprehensive Medicare AI/software Strategy

AI/SOFTWARE IN HEALTH CARE

AI/software and other digital health technologies have emerged as a key source of innovation and efficiency in health care. Investments in U.S. digital health companies grew from $1.6 billion in 2012 to a high of almost $30 billion in 2021, but declined in 2022.[8] Globally, market researchers estimated the health care AI market to be valued at $15.4 billion in 2022 and expect it to grow at a compound annual growth rate of 37.5 percent from 2023 to 2030.[9]

Increasingly, medical technology companies are leveraging AI and ML to create insights and innovations based on data generated during the delivery of health care to support better health

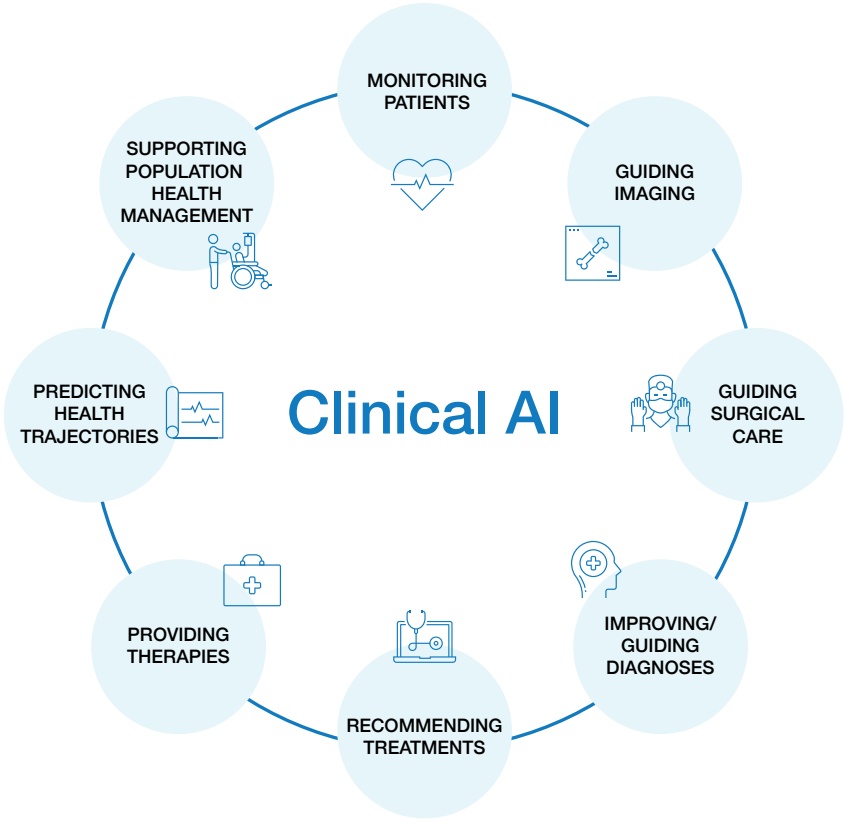
outcomes. While not an exhaustive list, the FDA has identified more than 500 AI/ML-enabled devices as having approval to be marketed in the U.S.[10] Additional AI/software solutions that do not meet the FDA definition of a regulated medical device are also supporting advancements in health care. All of these developments raise questions regarding how and if they will be covered and paid for under the Medicare program—as well as their potential to improve quality, health outcomes, and equity.

WHAT IS AI/SOFTWARE? HOW IS IT USED IN CLINICAL CARE?

The NAM uses the following definition of AI: "A collection of computer algorithms displaying aspects of human-like intelligence for solving specific tasks."[11] Within health care, software solutions may meet that definition of AI or use computing techniques such as advanced algorithms and ML that enhance the provisions of care without meeting the definition of AI. This report addresses Medicare coverage and payment for both AI and software, which support both clinical and administrative applications.[12]

In the clinical space, AI/software solutions support a range of needs and activities (**Exhibit 6**).[13] They can be used to monitor patients, guide surgical care, analyze images, predict health trajectories, recommend treatments, provide therapeutic interventions, and support population health management. For example, digital pathology, which enables management and interpretation of pathology information generated from a digitized glass slide, can transform into a digital medium that allows for more advanced analytics and predictive capabilities using AI/software.[14,15] AI/software can be a stand-alone product, an add-on solution to medical imaging or other devices/services, or a component of an implantable medical device. Innovations in AI/software may also raise the bar for the standard of care in medicine by increasing accuracy or speed of diagnosis and treatment.

Exhibit 6. AI/software Solutions Support a Range of Clinical Needs and Activities



Source: Adapted from Government Accountability Office. (2022, November 10). Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning Technologies for Medical Diagnostics.

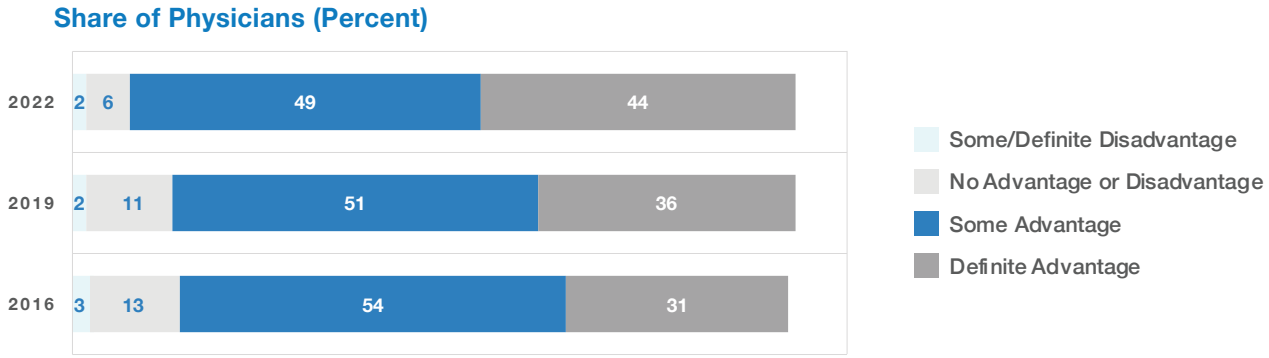
AI/SOFTWARE ACROSS THE CONTINUUM OF CARE

AI/software solutions may support care in a single setting, such as during an inpatient stay, or may collect data from one setting and deliver insights relevant to another setting, such as monitoring a patient at home and providing data and analytics to a clinician. Frequently, AI/software solutions leverage large datasets and real-time, cloud-based data analytics. These solutions provide an important connection across the continuum of care and allow for more complete tracking of a patient's condition(s) than is possible with periodic, in-person clinic visits. The implications for patients, providers, health plans and health systems, and population health are outlined below.

- **Patients.** AI/software tools support a patient-centered and consumer-driven health care experience, make timely care more accessible, and empower patients as leaders and partners in their own health journey. These tools may also allow for more convenient care. Some AI/software solutions provide health insights or therapies directly to an individual, such as digital glucose monitors, insulin pumps, or digital therapeutics that provide cognitive behavioral therapies. In these situations, a clinician may need to prescribe the technology and support the individual in learning how to use it.
- **Communities.** Benefits from the population health perspective are also apparent, in that AI/software and applications can help to reach underserved and vulnerable populations, identify individuals in need of care, manage chronic diseases, and support care management in the home and community. For example, technologies that allow an individual to remain in their home, connect with their care providers digitally, and receive community-based care can support addressing equity issues, social determinants of health, and access to needed care.
- **Payers.** In many cases, AI/software solutions can support earlier and better interventions for health conditions and provide better care coordination and more targeted treatments. With these tools, payers can provide the best set of services for individuals, increasing quality and, in some cases, reducing costs by allowing for earlier access to preventive services before conditions become acute.
- **Providers.** AI/software solutions may assist clinicians by providing and organizing data, augmenting diagnosis and treatment by offering analyses of the data, or acting autonomously by making and executing clinical decisions. In many cases, an AI/software solution will generate data and insights for a clinician such as physiologic monitoring of a patient or guidance to support the analysis of images or other data. Clinical decision support tools can help providers analyze large volumes of data and follow best practices. Predictive analytics can identify individuals or communities at risk of poor health outcomes and in need of care. Studies indicate that more should be done to support provider adoption of these innovative tools.[16]

According to the AMA, there has been a significant increase in the percentage of physicians that see advantages in leveraging digital tools of all types for patient care (**Exhibit 7**). That said, fewer than one in five physicians surveyed by the AMA had incorporated into their practices augmented intelligence for clinical applications or practice efficiencies.[17]

Exhibit 7. Physician Views on Digital Tools



Source: Adapted from American Medical Association (2022, September 28). AMA digital health care 2022 study findings.

A recent study by the NAM also noted the limited adoption of AI/software and ML tools by clinicians, even though they "are especially well suited to the problems of clinical diagnosis, shortening the time for disease detection, diagnostic accuracy, and reducing medical errors."[18] The study notes that better adoption of "AI diagnostic decision support (AI-DDS) tools could reduce the cognitive burden on providers, mitigate burnout, and further enhance care quality."[19]

The NAM study examines key factors limiting use of AI-DDS across four domains: reason to use, means to use, method to use, and desire to use. Among other issues, the authors identify lack of adequate reimbursement as a key constraint, pointing specifically to the limited mechanisms for direct reimbursement for AI-DDS under Traditional Medicare.[20] Further, a recent report from GAO highlighted additional challenges to adoption of diagnostic AI/software solutions. GAO made recommendations to improve the evaluation of real world performance, the availability of high-quality datasets, and collaboration among developers, providers, and regulators to improve and accelerate development and adoption.[21]

FEDERAL ROLES AND EMERGING POLICY ISSUES

FDA REGULATION OF AI/SOFTWARE VERSUS CMS COVERAGE

The FDA has statutory authority to assess the safety and efficacy of medical devices, including medical devices that involve AI/software. The FDA generally classifies medical device software into three categories, which were developed by the International Medical Device Regulators Forum:[22]

- Software as a Medical Device (SaMD)[23]
- Software in a Medical Device (SiMD)
- Clinical Decision Support Software[24]

AI/software solutions with medical functionality often require FDA clearance to be marketed and FDA has approved a growing number of products. As of October 2022, the FDA listed more than 500 AI/ML-enabled devices as having authorization to be marketed in the U.S. through 510(k) clearance, De Novo designation, or premarket approval (PMA).[25]

FDA clearance or approval of a technology does not guarantee coverage and payment by Medicare, as CMS considers whether a product or service is reasonable and necessary for its beneficiary population. However, stakeholders continue to push for better alignment between FDA clearance or approval of an innovative technology and the ability for Medicare beneficiaries to have timely access to important advances.[26, 27] As noted below, and in Part II's review of certain Medicare payment systems, CMS has included add-on payments to explicitly recognize new technologies in two settings—hospital inpatient and hospital outpatient. Even with these policies, there is a need for better and faster coverage and payment decision-making by CMS across all settings of care once an AI/software solution has been cleared by the FDA.

CPT TAXONOMY FOR MEDICAL SERVICES AND PROCEDURES

Effective January 1, 2022, the AMA's Current Procedural Terminology (CPT) code set includes a taxonomy for classifying artificial/augmented intelligence tools.[28] The taxonomy focuses on the relationship between AI applications and the clinical work involved in medical services and procedures. The AMA's Appendix S establishes foundational definitions for three types of AI:

- **Assistive:** The work performed by the machine for the physician or other qualified health provider (QHP) is assistive when the machine detects clinically relevant data without analysis or generated conclusions. Requires physician or other QHP interpretation and report.
- **Augmentative:** The work performed by the machine for the physician or other QHP is augmentative when the machine analyzes and/or quantifies data in a clinically meaningful way. Requires physician or other QHP interpretation and report.
- **Autonomous:** The work performed by the machine for the physician or other QHP is autonomous when the machine automatically interprets data and independently generates clinically relevant, meaningful conclusions without concurrent physician or other QHP involvement. Autonomous medical services and procedures include interrogating and analyzing data. The work of the algorithm may or may not include acquisition, preparation, and/or transmission of data. The clinically relevant meaningful conclusion may be a characterization of data (e.g., likelihood of pathophysiology) to be used to establish a diagnosis or to implement a therapeutic intervention. Autonomous AI includes three levels, which vary by the extent of physician or other QHP professional involvement.[29]

While the new taxonomy is specific to CPT coding, it also provides foundational definitions to understand what a given AI solution accomplishes vis-à-vis clinical work and allows for differentiation among AI solutions.

The taxonomy does not drive coverage or payment by Medicare, other federal health programs, or private sector payers. However, it will likely have downstream impacts by supporting a more consistent set of considerations for understanding how a given AI/software solution works, which could support more accurate coverage considerations and payment policies by CMS and other payers. At the same time, policymakers and private payers should not assume that the cost and the potential value of an AI solution are the same within a given classification of AI (assistive, augmentative, autonomous), or that the cost and value are necessarily higher for one classification over another. Although costs of a given solution are unique to the value it brings and the inputs that are required—the taxonomy should help inform CMS' development of an agency-wide framework for considering AI/software solutions.

WHITE HOUSE AND HHS ACTIVITIES

The increased use of AI and other software tools across health care has received attention at the highest levels of government. The White House Office of Science and Technology Policy (OSTP) established a National Artificial Intelligence Initiative Office to coordinate federal activities in AI. The White House and OSTP have also focused on both the extraordinary benefits and potential harms of AI for civil rights, such as questions of privacy and non-discrimination and are working with large technology companies on responsible deployment of AI.[30] In fall 2022, OSTP released a Blueprint for an AI Bill of Rights that includes five principles[31]:

- Safe and effective systems
- Algorithmic discrimination protections
- Data privacy
- Notice and explanation
- Human alternatives, consideration, and fallback

Within HHS, the Office of the Chief Artificial Intelligence Officer was established in 2021 in order to drive implementation of the HHS AI strategy, including governance, coordination, and collaboration across agencies within HHS.[32] CMS and other agencies within HHS, such as the Office of the National Coordinator for Health IT,[33] have begun to focus on AI as a crucial source of innovation in health care, while seeking to understand the appropriate safeguards to minimize and mitigate unintended consequences, including the introduction of bias or inequalities in outcomes.[34] In addition to concerns about identifying and mitigating bias, the Administration is prioritizing transparency about how AI/software solutions work. Among other issues, the Administration is focused on greater transparency around the data used to develop and test products.

EQUITY

Unfortunately, recent analyses have shown that some algorithms and other AI/software solutions can perpetuate existing biases in health care if developers do not carefully assess the underlying data used to train them for fairness, monitor their performance, and make changes to address any issues found. This is because the data used in developing AI/software may reflect existing inequities in health care or be unrepresentative of the full population. In addition, bias or inequity may result from the choices made in collecting data and model development.[35] For example, researchers found that inclusion of a factor that adjusted for race in an algorithm used to classify the severity of kidney disease could unintentionally lead to bias in care delivery.[36]

ETHICAL AI

Increasingly, policymakers, researchers, and developers have focused on ethical approaches to develop and deploy AI/software. For example, Abramoff, Tobey, and Char identified evaluation criteria for autonomous AI that include consideration of "patient outcome, validation, reference standards, design, data usage, and accountability for medical liability."[37] The collection and use of data for AI/software also raises questions of privacy and consent that must be addressed. Steps to ensure ethical approaches in development of AI/software solutions are increasingly being discussed, and some researchers are developing methods to assess AI/software for detection of bias.[38] The FDA has also prioritized detection and mitigation of bias as a regulatory metric in evaluating AI/software products.[39] Also, studies have found that the systematic and data-driven outcomes of AI/software solutions can reduce the existing bias in the health care system.[40] As discussed further below, Medicare must develop its own guardrails to ensure ethical and equitable use of AI/software.

UNIQUE ATTRIBUTES AND COSTS OF AI/SOFTWARE

Innovative technologies will increasingly leverage the power of data and analytics to improve quality of care, health outcomes, and advance health care transformation. For benefits to be fully realized and payment to be fair, the Medicare program should pay careful attention to AI/software's role in care delivery, its unique attributes and costs, as well as the impact of these innovations on equity and ethical use. All relevant stakeholder's viewpoints—patients, caregivers, providers, payers, and innovators—should be considered to promote quality of care and to mitigate unintended bias in Medicare's payment pathways.

In establishing payment policies, CMS reviews the costs of goods and services across benefit categories which are specific to a given patient and care setting, such as an inpatient stay or an outpatient surgery. Medicare's payment systems are designed to cover the marginal costs of efficient providers. Thus, determining the costs of those items and services by benefit category generally

requires understanding site-specific costs for a given set of inputs. However, AI/software can span several sites of care and have cost inputs that are different from the traditional items and services that CMS currently assesses.

For example, AI/software solutions can acquire data from multiple sources, analyze that data either within a device or piece of equipment used in a specific setting or in a remote location, and share data outputs in the form of insights or specific actions that drive care. These more complex interactions between a setting of care and the AI/software solution may create a set of costs that arguably vary from the traditional model of input costs used in Medicare's payment systems for a given benefit category or setting for a specific patient. **Exhibit 8** summarizes the unique costs Medicare should consider in its payment decisions for AI/software within and across benefit categories.

Exhibit 8. Unique Input Costs of AI/software for Providers, Payers, and Manufacturers*

AI/Software Input Costs for Providers/Payers	AI/Software Input Costs for Manufacturers

• **Devices and other hardware** needed to collect data from an individual patient
• **AI/software solutions** for clinical care of patient
• **Integration into electronic health records** and other existing IT systems
• **Personnel and workflow changes** to support and act on new data flows
• **Connectivity** to support transmission of data for analysis
• **Operating and Capital Costs** incurred to support use and updating of AI/software over time
	• **Capital costs for:**
	  ▪ Computing power to conduct analyses that may require processing of large data sets
	  ▪ Maintaining and updating systems (including cybersecurity) over time
	  ▪ Data storage and connectivity capabilities
	• **Engaging in clinical research** and development to provide innovative solutions that advance standards of care
	• **Updating algorithms over time** to address changes in clinical data, outcomes, and changes in standards of care
	• **Compliance with regulatory requirements:**
	  ▪ For initial development
	  ▪ For periodic updating of products over time, as required by FDA

*Note that some entities may serve both the provider and manufacturer functions.

Source: CapView Strategies/AdvaMed Analysis

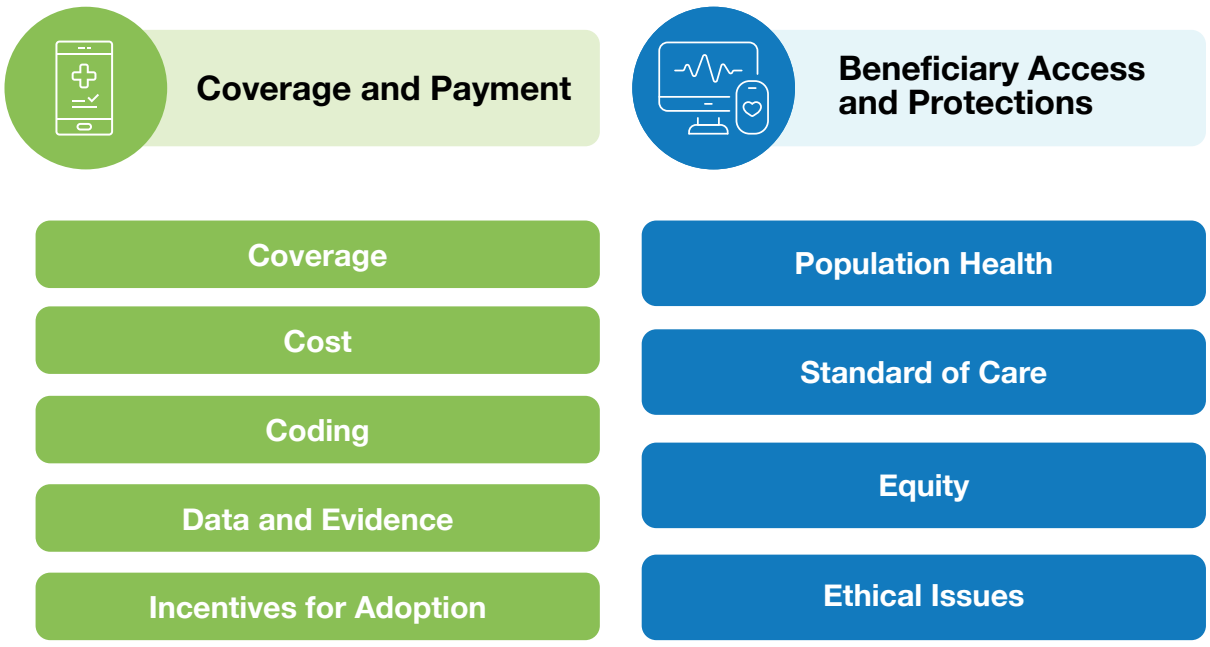
CORE CONSIDERATIONS

As the development and use of AI/software solutions grows, CMS will need to look across its payment pathways to ensure that the Agency takes a systemic, evidence-based, and fair approach to coverage and payment (**Exhibit 9**). The recommendations in this report focusing on Medicare's benefit categories, MA, and APMs (see Part II) offer some promising solutions, and also show that the site of service and the size of the payment bundle are factors that may lead to different methodologies.

Additionally, interviews with experts from manufacturing companies and a review of the literature found that Medicare's policies lack a comprehensive, systematic approach for recognizing the unique attributes and costs of these technologies. A more comprehensive solution is needed across and within benefit categories.

The set of core considerations presented below may guide CMS in developing a more systematic methodology in making coverage and payment decisions, in protecting beneficiaries' access and privacy, and in promoting health equity and ethical use. By employing these core considerations, CMS can ensure that coverage and payment decisions recognize the innovation's value for clinical care and population health, as well as its unique attributes and costs.

Exhibit 9. Crosscutting Issues in Medicare Payment Systems



Source: CapView Strategies/AdvaMed Analysis

CORE CONSIDERATIONS ON COVERAGE AND PAYMENT:

- **Coverage.** CMS should be clear on the criteria for coverage of AI/software in a way that is consistent across benefit categories including:
  - Recognition that FDA approval/clearance of a technology is required, including for breakthrough devices, which applies across all payment systems; and
  - Clarity in how CMS categorizes AI/software using consistent language across payment systems (including but not limited to consideration of the AMA Taxonomy).

- **Cost.** CMS should clarify the parameters it will consider in developing payment rates for AI/software, including those solutions that are part of a larger bundled payment or eligible for a new technology payment. For example:
  - Recognition that AI/software solutions include a unique range of costs, including those for collecting data, conducting analyses that require significant computing power, maintaining and updating algorithms, and addressing FDA requirements for ongoing monitoring and potential reapproval;
  - Adequate payment to cover the marginal cost of a service, as well as some recognition of development costs to reward and incentivize innovation;
  - Recognition of the potential of AI/software solutions to speed diagnosis, improve health care outcomes, and reduce spending on other health care services; and
  - Consideration of the business models that are used by AI companies, including subscription models, licensing, and add-on costs tied to capital equipment (such as imaging equipment).

- **Coding.** Medicare uses the Healthcare Common Procedure Coding System (HCPCS) to establish codes for physician services and other benefits or services. CMS should develop a clear set of guidelines for establishing AI/software codes, including the rationale for when a category of codes will be developed for a set of solutions (such as the remote patient monitoring/remote therapeutic monitoring codes) versus when a code will be established for a given AI/software solution. CMS should adapt its coding process and assignment of codes to address the unique attributes and diffusion of AI/software.

- **Data and Evidence Standards.** CMS should provide clear guidance on the data and evidence standards necessary for coverage and payment across benefit categories, including:
  - Data needed to support coverage of an AI/software solution as medically reasonable and necessary;
  - Criteria to be considered to ensure that a given AI/software solution is unbiased and ethically developed;
  - Criteria to be considered for determining when an AI/software solution fits within an existing payment bundle, is considered a stand-alone service, or is eligible for a new technology payment; and
  - Clarity on when the use of real-world evidence can support coverage and payment decisions, including how these data may apply across different settings of care and population groups.

- **Incentives for Adoption.** AI/software can change the delivery and standards of care and has the potential to improve quality and health care outcomes—CMS should provide incentives for adoption by ensuring adequate payment. This could entail including AI/software in quality programs and collaborating with stakeholders to address how AI/software can support clinicians by improving workflows and reducing other burdens.

CORE CONSIDERATIONS ON BENEFICIARY ACCESS AND PROTECTIONS:

- **Standard of Care.** CMS should review the ways in which AI/software can advance care delivery and standards of care, both within and across benefit categories and payment systems.
- **Population Health.** CMS should acknowledge that AI/software allows for use of data to create new knowledge to improve population health. For example, such as managing the care of a designated population by looking at factors beyond the services provided to individuals and taking into account total costs across the continuum of care.
- **Equity.** CMS should work with stakeholders including patients, providers, and innovators to identify appropriate guardrails to assure that AI/software is developed and deployed to minimize bias and disparities in its use in health care.
- **Ethical Issues.** CMS should collaborate with stakeholders to identify appropriate guardrails to assure that decision-making processes embedded in the use and deployment of AI are focused on advancing quality, outcomes, and patient safety— and avoiding malfeasance and incentives purely focused on the AI's proliferation. Ethical AI should also consider and assure the ability to protect privacy.

VALUE AND GUARDRAILS

Innovative AI/software solutions can bring value to patients through improved quality, health outcomes, and better care coordination across services and settings. These technologies can facilitate early interventions and help avoid exacerbations of chronic diseases, generate data for clinicians to use in care management, and provide more accurate diagnostic testing information that will support early diagnosis and limit the need for repeat tests. AdvaMed's recently published Framework outlines five categories of value drivers: clinical impact; non-clinical patient impact; care delivery revenue and cost impact; public and population impact; and environmental impact.[41]

As CMS begins to assess the drivers of value for AI/software in Medicare, it should consider a technologies' impact on quality of care, implications on total costs of care, population health issues, and equity. These issues may be particularly relevant in Medicare's value-based payment programs, APMs, MA, and in other initiatives addressing costs, quality, and equity in health care.

GUARDRAILS

The core considerations for Medicare are foundational to establishing appropriate guardrails for coverage and payment of AI/software as CMS explores issues related to ethical use, changing standards of care, data and evidence requirements, and equity of care. The development of guardrails will also set expectations about necessary steps to help protect Medicare beneficiaries and assure quality of care in the use of AI/software in the Medicare program.

In developing strategies to improve coverage and payment for AI/software in Medicare, policymakers must also collaborate with stakeholders across government and the private sector to define guardrails to ensure appropriate, ethical, and non-biased use. Steps should be taken to eliminate privacy concerns for patients and providers across the health care system. Appropriate guardrails will be essential to improving population health and quality and in protecting beneficiaries from unintended consequences.

COMPREHENSIVE MEDICARE AI/SOFTWARE STRATEGY

Innovation in AI/software is occurring at a brisk pace as the ability to collect, analyze, and use data to manage patient care grows. AI/software solutions are helping to re-envision the delivery of health care for patients, caregivers, and providers not only in Medicare but also in the entire health care sector. CMS has the regulatory flexibility to address access to these innovative technologies to improve care for patients. As the largest payer, CMS should harness its marketplace power to advance a comprehensive strategy on AI/software solutions to meet the challenges of improving care and reducing costs. The comprehensive strategy outlined below defines a path forward.

The Comprehensive Medicare AI/software Strategy (**Exhibit 10**) leverages CMS' leadership role in health care to create new collaborations and partnerships. The strategy also develops a more systematic approach to coverage and payment in Medicare and uses CMS' marketplace power to create consensus on how best to value AI/software innovations, and to put in place appropriate beneficiary protections and guardrails. The comprehensive strategy outlines steps for the Agency to:

- **Strengthen CMS Leadership.** As a first step, CMS should appoint a Chief AI Officer, charged with improving collaboration across the government and with private sector stakeholders, including patients, providers, payers, and manufacturers.
- **Take Action on Key Policy Issues:** The CMS Chief AI Officer should lead the comprehensive strategy and assure key foundational steps are taken for the ethical, equitable, and privacy-protecting deployment of innovative AI/software technologies. The specific steps include:
    - **Implementing targeted recommendations.** A key step in the policy strategy is to build on the regulatory flexibility available to CMS for coverage and payment of innovative AI/software technologies. In continuing efforts to improve payment policies, CMS should

implement the 25 targeted recommendations outlined in Part II of this report. Serving as the underpinning for future policy decisions, this step would create an accurate and consistent approach for moving forward in addressing coverage, cost, and data issues for AI/software by Medicare.

- **Addressing core considerations.** CMS should evolve its policies to account for the unique features, functions, and costs associated with the use and development of AI/software. The core considerations should guide Medicare's coverage and payment decisions, as well as those focusing on beneficiary access and protections. The core considerations should apply not only to Medicare, and each of the program's benefit categories, but also to the role of AI/software in the changing health care system, moving to personalized, community-oriented solutions, and value-based care initiatives.
- **Incorporating guardrails and assessing value.** CMS must ensure that AI/software technologies used in the care of patients advance quality of care and health outcomes. AI/software solutions should be appropriate, ethical, and non-biased, while protecting the privacy of beneficiary information. CMS should collaborate with stakeholders and other federal agencies to identify specific value drivers and guardrails, such as data and evidence needs, transparency requirements, appropriate monitoring tools over time, and links to quality measures. Guardrails will be essential to maximizing the potential of these technologies, while also establishing appropriate beneficiary protections.

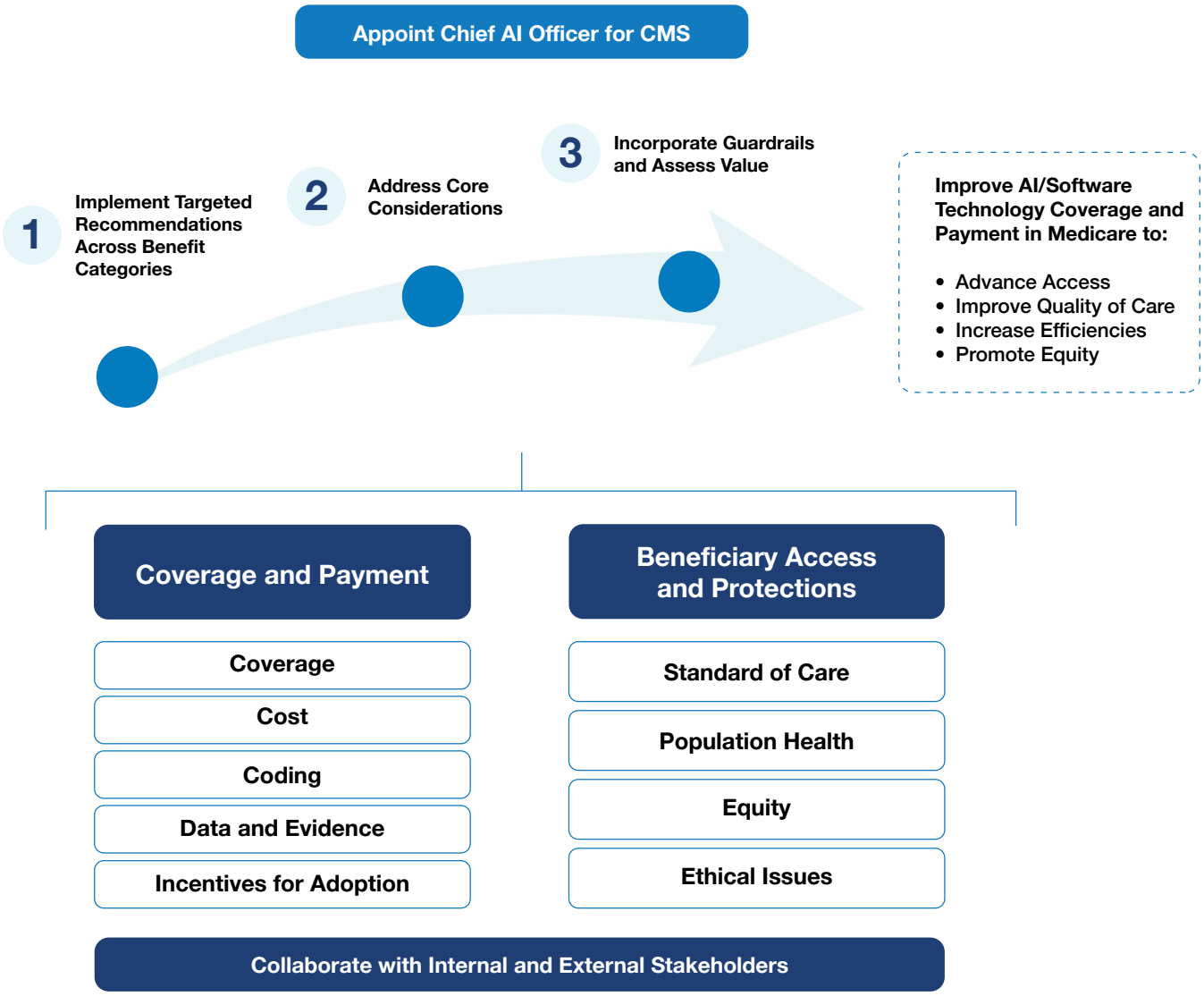
- **Leverage Medicare's Marketplace Power.** As CMS' policies evolve to better incorporate AI/software into Medicare, this new comprehensive strategy creates a system-wide approach to coverage and payment across settings. It strengthens current payment policies to ensure beneficiaries have access to new technologies, while also addressing the core considerations key to the ethical development and use of new, innovative AI/software in Medicare, and across health care.

The strategy will strengthen current payment policies and create a more systematic and transparent process for coverage and payment in Medicare. Additionally, patient-centered issues will be addressed to:

- Recognize the impact of AI/software in speeding diagnosis and screening, improving health outcomes, advancing the standards of care, and reducing spending on other health care services; and
- Leverage AI/software to address equity, social determinants of health, and disparities in health care.

By establishing new partnerships across government agencies and with the private sector—and importantly with patients and caregivers—CMS can facilitate the exchange of lessons learned and best practices to harness AI/software safely and appropriately for the benefit of all. The time is now for CMS to take a leadership role on coverage and payment issues for AI/software in Medicare and across the health care sector.

Exhibit 10. Comprehensive Medicare AI/software Strategy



Source: CapView Strategies/AdvaMed Analysis

Part II. Targeted Recommendations to Improve Coverage and Payment

Recent innovations in AI/software have demonstrated diagnostic, therapeutic, preventive, and monitoring capabilities that stand to improve health and care across all Medicare benefit categories and payment systems. Medicare beneficiaries can benefit from AI/software used in an outpatient clinic, a hospital or other institutional setting, or at home. Among the many innovations currently available, AI/software tools can:

- Perform an entire outpatient service, such as an eye exam;
- Collect blood pressure and other digital biomarkers at home for use in clinical decision-making;
- Provide therapy to individuals in their homes;
- Remotely monitor individuals' response to therapy;
- Decrease the time to emergency department and inpatient treatment for patients experiencing a stroke;
- Use machine learning techniques to guide the taking and reading of digital images in inpatient and outpatient settings;
- Support and guide surgeons using surgical robots in inpatient and outpatient settings; and
- Offer tools to enhance the ability of pathologists to identify cancers and other diseases.

As noted in Part I, as the largest payer, CMS must develop a systematic approach to incorporating AI/software across Medicare benefit categories that recognizes the growing and essential role in health care of these technologies. CMS must also determine whether a given AI/software fits into one of the benefit categories outlined in statute (e.g., physician services, inpatient and outpatient hospital services, durable medical equipment, etc.) and whether the technology is reasonable and necessary for the Medicare population. Most items and services used to care for an individual patient must also be identified through a unique code. Once a technology is determined to fit in a benefit category, CMS must address it in the complex regulations governing the discrete payment systems. Each payment system has unique characteristics, such as the size of the bundle and the ways in which new technologies are incorporated. Therefore, improving the coverage and payment of AI/software solutions also requires addressing it in the distinct structure of each payment system.

Part II presents a detailed regulatory analysis of Medicare's coverage and payment pathways for AI/software. CapView's comprehensive review resulted in targeted, high-level recommendations across Traditional Medicare, Medicare Advantage (MA) and alternative payment models (APMs) (**Exhibit 11**).

The following sections review Medicare's payment systems to:

- Describe recent steps by CMS to address coverage and payment of AI/software;
- Identify remaining issues by payment system; and
- Offer targeted recommendations.

Within Traditional Medicare, the report examines the payment systems for hospital inpatient and outpatient care, physician services, including independent diagnostic testing facilities (IDTFs), and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). In addition, **Exhibit 21** on page 42 describes the current treatment of AI/software under the clinical laboratory fee schedule. CMS will need to collaborate with stakeholders to determine how best to operationalize these targeted recommendations and incorporate specific AI/software solutions. The lessons learned from this detailed regulatory analysis inform the new comprehensive Medicare AI/software strategy proposed in Part I.

Exhibit 11. Coverage and Payment Pathways for AI/software Under Medicare

Medicare Benefit Category	New Technology Adjustment	Recent Developments in AI/Software Coverage
Inpatient Hospitals IPPS	Yes NTAP	• Inclusion of AI/software and recognition of subscription model in NTAP
Outpatient Hospitals OPPS	Yes New Technology APCs and TPT Payments	• RFI on coverage of SaaS • Separately payable codes for software analyses
Physician Services (Including IDTFs) MPFS	No	• Coverage of autonomous AI • Expansion of RPM/RTM
DMEPOS	No	• Denial of coverage for some digital therapeutics • Coverage of virtual reality solution (with equipment)
Medicare Advantage CAPITATED PAYMENT SYSTEM	N/A	• Potential to include AI/software technologies in supplemental benefits
Alternative Payment Models MODEL SPECIFIC	N/A	• AI challenge and recognition of potential in value-based payment

Source: CapView Strategies/AdvaMed Analysis

INPATIENT PROSPECTIVE PAYMENT SYSTEM

Medicare pays for acute hospital inpatient care under the inpatient prospective payment system (IPPS) through established rates for hospitals' operating and capital costs.[42] These costs are then

adjusted for case mix by assigning each patient's stay to a severity related diagnosis group based on the clinical condition(s) and treatment strategy.[43] These bundled costs are established as Medicare Severity Diagnosis Related Groups (MS-DRGs).[44] Technologies which include AI/software may be incorporated into the MS-DRGs if they are a key component of patient care services. However, there is a two- to three-year time lag for updating allowable costs within MS-DRGs and the relative weights that determine payment amounts, which may create barriers to adoption. New and costly technologies used for inpatient stays may, in some cases, be eligible for a short-term, additional payment under the inpatient new technology add-on payment (NTAP).

KEY ISSUES FOR MS-DRGS

Given the large payment bundle and time lag for updating the relative weights, the IPPS may not adequately account for the cost of AI/software in the MS-DRG, or value it appropriately as a capital expenditure.

- **MS-DRG bundles.** The large bundles under IPPS mean that payment rates are the same for certain services regardless of whether the provider is using AI-enhanced products that improve quality and outcomes. This approach provides a disincentive to adopt technologies that may pose incremental costs but provide real improvement in care and health care outcomes. For example, assistive technology for surgery improves accuracy, resulting in a shorter recovery time after hospitalizations.
- **Capital costs.** Many AI/software solutions include capital costs for the provider, such as integration into existing IT systems and adequate connectivity. It is not clear in IPPS whether the capital costs of implementing new technologies are sufficiently reflected in the related elements of the payment system, such as the annual updates to the MS-DRG relative weights and the per-case capital payments. This is because of the complex mechanisms used to update these factors and the time lag for the data used.
- **Delayed recognition of costs.** The methodology for setting relative weights relies on analysis of historic claims and cost reports. Therefore, the IPPS does not recognize the costs of new AI/software solutions incorporated into a MS-DRG until after technologies have been purchased and the associated costs are reflected in the relative weights. The only exception is when AI/software solutions qualify for the inpatient NTAP.

NEW TECHNOLOGY ADD-ON PAYMENTS

Importantly, new and costly technologies used for inpatient stays may be eligible for a short-term additional payment under the inpatient NTAP. To be eligible for the add-on payment,[45] the technology must meet specific criteria to demonstrate that it is:

- New,
- Costly such that the MS-DRG rate would be inadequate, and
- Provides substantial clinical improvement over existing services/technologies.

In 2020, CMS created an alternative pathway for devices that are part of FDA's Breakthrough Devices Program and receive FDA marketing clearance that allows them to more easily meet the NTAP criteria.[46] The breakthrough approval will automatically meet CMS' requirements for newness and the Agency will waive the need to demonstrate substantial clinical improvement.

A stated goal of the NTAP is to provide payment for a beneficial and costly new technology while adequate cost data are accumulated to support a fair and accurate payment amount for the related MS-DRG. However, NTAP payments by design do not cover the full costs of the technology.[47, 48] In addition, during interviews for this report, device companies expressed concerns that current coding and cost reporting practices by hospitals and other providers may not be sufficient to ensure accurate reweighting of the relevant MS-DRG relative weights. This could happen if, for example, a hospital uses the technology but fails to either include the NTAP code on its claim or appropriately include the related costs on its cost report.

RECENT CHANGES BY CMS

CMS approved several AI/software solutions for the NTAP in each year from 2020 through 2023 and has proposed additional NTAP determinations for 2024. These technologies include, among others, triage and notification software that accelerates the diagnosis and treatment of large vessel occlusion (LVO), computer-aided diagnosis of brain tissue abnormalities on brain CT images, and an autonomous tissue removal robot for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia.[49] Notably, for the first time, the payment rate for one of these technologies was based on the costs of a subscription model for hospitals, meaning that the hospital paid a subscription rate for use of the technology rather than purchasing it outright. This development aligns with the growing use of subscription models for these AI/software solutions.

These are important first steps in addressing AI/software in the IPPS, yet more can be done to incorporate the unique features of AI/software in a system developed for more traditional medical technologies. For example, traditional medical technologies do not employ cloud-based data systems and analytics to inform clinical decision-making, which are often intrinsic features of AI/software in medical devices.

KEY ISSUES FOR NTAP

The NTAP criteria (newness, cost, and substantial clinical improvement) pose a high bar that limits the ability to bring innovative solutions to inpatient care. Consequently, lower cost AI/software solutions are often excluded from the NTAP due to the cost criterion, particularly if they are used in treatment of patients assigned to high-cost MS-DRGs.[50]

Additionally, NTAP qualifying criteria are often too limited to support innovative technologies. More guidance is needed from CMS on appropriate data necessary to meet the criteria of newness and substantial clinical improvement, particularly regarding the role of real-world evidence.[51, 52, 53]

- **Addressing cost of AI/software in NTAP.** Even with NTAP status, the add-on payment does not cover the full cost of the technology and requires the hospital to experience a loss when using a new technology, disincentivizing the adoption of technologies that improve patient care.[54]
- **NTAP cost data.** More data on the costs of using AI/software need to be captured by providers and reported to CMS during the period a technology is eligible for NTAP. This would allow for better reflection of costs when the technology loses its NTAP status and CMS must incorporate its costs into the MS-DRGs weights. Specifically, more information is needed about the capital and operating costs associated with AI/software under NTAP.
- **Post-NTAP status.** The first AI/software items are now losing their NTAP status and being incorporated into base MS-DRG payments. Given the newness of NTAP payments for AI/software, and potential limitations in hospital coding of use, it is unclear if CMS has sufficient data to appropriately account for the costs of AI/software after the NTAP status expires. In addition, it is unclear how the reweighting of the MS-DRGs accounts for situations when a screening diagnostic technology approved for NTAP results in a negative test.

Exhibit 12. Recommendations to Address AI/software Challenges in IPPS

- **Recommendation IP.1—Accurately reflect costs of AI/software when updating and reweighting MS-DRGs.** CMS should review its processes for updating and reweighting MS-DRGs to ensure more complete, accurate, and timely incorporation of costs associated with AI/software technologies.
  - **Methodology for updating MS-DRGs.** CMS should explain how AI/software costs are currently incorporated into MS-DRGs, including specific examples of how costs for these technologies are captured when MS-DRGs are updated and reweighted and any possible barriers. CMS should also consider any needed improvements, which could include changes to the cost report to better capture specific costs.
  - **Capital costs.** CMS should provide greater transparency on how hospitals' capital costs associated with AI/software are reflected in its updates to the relative weights and the IPPS capital payments. CMS should assess whether the hospital cost report and capital market basket adequately capture the capital costs of new technology investments.
  - **Timeliness of reweighting.** CMS should evaluate the extent to which reweighting of MS-DRGs adequately incorporates the costs of AI/software, especially for technologies that transition out of NTAP status.

Exhibit 12 Continued

- **Recommendation IP.2 — Strengthen the NTAP to include AI/software technologies.** CMS should review its policies to accurately incorporate AI/software in the NTAP.
  - **Recognize full array of costs.** CMS should ensure that its consideration of AI/software solutions under the NTAP recognizes the full suite of costs associated with AI/software incurred by providers and manufacturers, including unique costs for collecting data, conducting analyses that require significant computing power, and maintaining and updating systems (including cybersecurity). Further, CMS should consider how capital costs are included in the NTAP.
  - **Improve provider cost data on NTAP.** CMS should include requirements for providers that benefit from NTAP to collect data on the specific costs incurred to use a technology, including both subscription costs (as appropriate) and related capital and operating expenses. This would ensure that base MS-DRG payments adequately account for the costs of AI/software once NTAP status has ended.
  - **Clarify evidence requirements.** CMS should provide guidance on how real-world evidence can be used to meet the NTAP criteria (separate from the types of evidence enumerated in 42 C.F.R. § 412.87).

OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

Under the outpatient prospective payment system (OPPS), Medicare generally pays for outpatient hospital services based on ambulatory payment classifications (APCs). For each comprehensive APC, CMS bundles integral services and items with the primary service.[55] Technologies are assigned to APC cost groupings based on resource and clinical criteria. However, some items are separately payable under the OPPS and are not bundled into an APC. The OPPS also includes two mechanisms to at least partially recognize the added costs of innovative new technologies: New Technology APCs and transitional pass-through (TPT) payments (**Exhibit 13**).

KEY ISSUES FOR APCs

While CMS has some mechanisms to address new technologies in the OPPS, the core system of comprehensive APCs lacks incentives to adopt new AI/software because new costs will not be reflected in payment rates in the early stages of use. Furthermore, meaningful updates to AI/software used for items or services within an APC are not paid for under the current payment system even if they offer improvements in care or efficiency of care delivery. For example, the payment rate for an existing surgical APC may not reflect updates to the existing software systems that support the surgeon. Additionally, the methodology does not account for the potential value of the improvements on outcomes and reduction of downstream costs from AI/software updates.

Exhibit 13. Payment Mechanisms in the Medicare OPPS

	Ambulatory Payment Classifications (APCs)	New Technology APCs	Transitional Pass-Through Payments
Description	Bundled payment that varies in size from comprehensive services to separately paid items	Complete service that is too new for CMS to have accurate data to set relative weights	New and costly technology that is part of an existing APC
Inclusion Criteria	Grouped based on services and clinical criteria	Grouped based solely on costs	Application process to determine qualification
Payment	Payment based on relative weights	Payment based on the mid-point of a cost range	Application process to determine payment amount

Source: CapView Strategies/AdvaMed Analysis

RECENT CHANGES BY CMS

Separately payable codes. In addition to the comprehensive APCs, CMS pays separately for certain items and services, such as inter-ocular lenses (IOLs), corneal tissue acquisition costs, blood and blood products, and drugs and biologics whose costs exceed a threshold ($130 per day in 2022).[56] Recently, CMS has also paid separately for certain new technologies like HeartFlow (a non-invasive diagnostic test to identify the impact that blockages have on blood flow to the heart) and in the 2023 final rule CMS approved other Software as a Service (SaaS) technology (LiverMultiScan, Optellum) to be paid as an add-on if done at same time as an imagining procedure or separately if done at later time.[57] CMS finalized its proposal to accurately capture costs. It is positive that CMS is making separate payments for add-on codes as an exception to its longstanding OPPS packaging policy; this will more appropriately reflect such costs in the OPPS.

RFI on paying for SaaS under OPPS. It is significant and positive that CMS included a request for information (RFI) concerning payment for SaaS in its CY 2023 OPPS Proposed Rule (**Exhibit 14**). As the use of SaaS increases, incorporating stakeholder perspectives on appropriately covering these services is a step in the right direction. However, CMS should carefully consider the options presented to ensure the most flexible approach to payment. As CMS continues to develop these policies, the Agency should clarify distinctions in technologies and make sure they account for the variety of SaaS and AI/software to be covered.

Exhibit 14. Approaches to Paying for SaaS in OPPS

In the 2023 OPPS proposed rule, CMS requested input on three approaches to paying for SaaS:

1. Package payment for the underlying service (such as imaging) and the SaaS procedure in a single HCPCS code and APC.
2. Expand comprehensive APCs to include both the underlying service and SaaS.
3. Use individual HCPCS codes to describe the underlying service, the SaaS procedure, and the combined service, using a New Technology APC to pay for both services.

KEY ISSUES FOR NEW TECHNOLOGY APCs

New Technology APCs are used for complete services that are too new to be represented in the data used to develop the initial payment rates for the OPPS. They are defined by cost ranges rather than clinical classifications. Services remain in new technology APCs for two to three years, while CMS collects the data necessary to better classify and develop specific payment rates for them.[58]

AI/software solutions belong in the New Technology APCs when the AI/software technology is the primary service provided, or a significant component of the primary service provided, and the Agency does not yet have sufficient cost data to accurately set a payment rate for the primary service inclusive of the AI/software cost.

It is important to understand that New Technology APCs are distinct from the TPT payments, which reflect the costs of innovative implantable technologies that are associated with an existing procedure or service, as discussed below.

KEY ISSUES FOR TPT PAYMENTS

TPT payments support new technologies, including devices, which are part of an existing service or procedure described by an APC. To be eligible for TPT payments, a device must be reasonable and necessary, integral to the services provided and meet the following requirements:

- Recently cleared by the FDA (within 3 years);[59]
- Not appropriately described by another existing category or one previously established for TPT; and
- Substantial clinical improvement over currently available treatments.

Additionally, the costs for a new technology must be “not insignificant” relative to the payment amounts for the service or procedure to receive TPT payments.[60, 61]

TPT designation lasts for three years and allows CMS to collect data on costs and assign the

designated technology to the appropriate APC. However, TPT payments are required to be budget neutral and can only account for two percent of estimated total OPPS payments across all designated devices and other products.[62] By contrast, the NTAP under the IPPS provides new funding without regard to budget neutrality.

Beginning in 2020, CMS finalized the creation of an alternative TPT pathway for devices approved under the FDA Breakthrough Device Program, meaning that devices with a breakthrough designation are exempt from meeting the substantial clinical improvement criterion.[63] However, issues with the TPT remain:

- **Need to recognize full costs associated with AI/software.** The pass-through designation is limited to implantable/insertable devices that are used for one patient only. Furthermore, the criteria and methodology to qualify for TPT payments may limit its availability for novel AI/software products. These limitations include requirements for cost thresholds, establishing newness, and providing evidence for substantial clinical improvement for AI/software outside of the alternative pathway.
- **Need for clarity on evidence for substantial clinical improvements for AI/software.** More guidance is needed from CMS on the data and evidence necessary for AI/software solutions to meet the TPT criteria requirements for substantial clinical improvement. CMS has not issued regulations for TPT to clarify substantial clinical improvement the way it has for NTAP.
- **FDA breakthrough designation.** While breakthrough status allows new devices to automatically meet the substantial clinical improvement criteria for TPT payments, it does not automatically address the newness criteria used in CMS policies.

Exhibit 15. Recommendations to Address AI/software in OPPS

APCs

- **Recommendation OP.1—Adequate consideration of costs in comprehensive APCs.** CMS should factor the full range of AI/software costs into its payment rates/bundles including unique costs for collecting data, conducting analyses that require significant computing power, and maintaining and updating systems (including cybersecurity). CMS should include the costs for updates to technologies over time (including FDA-required updates and technical updates) in determining changes in payment for separately payable or bundled codes for AI/software functions over time.
- **Recommendation OP.2—Modifier for incremental costs.** CMS should consider a modifier to the billing code for AI/software additions to comprehensive APCs to allow the Agency to better understand the incremental costs associated with some new AI/software technologies that are not placed in a New Technology APC and do not qualify for TPT

Exhibit 15 Continued

payments. The modifier will allow CMS to more accurately incorporate the associated costs into the recalibration of weights over time.

SaaS

- **Recommendation OP.3 - Unique features of SaaS.** CMS should acknowledge that not all SaaS should be paid the same amount under the OPPS and review whether payment approaches for SaaS adequately account for data complexity, collection, use, and updates by:
  - Separately evaluating each new technology to determine the appropriate HCPCS coding, including whether or not a potential CPT code can be used to support payment for the separate and distinct service under the OPPS.
  - Considering separately payable codes for SaaS where appropriate in circumstances when the cost of the AI/software would not be adequately covered if included in the bundled service.
  - If not separately payable, considering whether a service should be assigned to a higher cost APC when use of SaaS results in discrete and incremental costs.

New Technology APCs

- **Recommendation OP.4—AI/software in New Technology APCs.** CMS should include AI/software solutions in the New Technology APCs when the AI/software technology is the primary service provided, or a significant component of the primary service provided. This will allow the Agency to collect sufficient cost and claims data to appropriately assign the primary service, inclusive of the AI/software cost, to a permanent clinical APC.

TPT Payments

- **Recommendation OP.5—Adequate consideration of costs in TPT payments.** CMS should ensure that its consideration of AI/software solutions under the TPT payments recognizes the full suite of costs associated with AI/software, including unique costs for collecting data, conducting analyses that require significant computing power, and maintaining and updating systems (including cybersecurity). As more technologies are developed utilizing AI/software technologies that have components that qualify as capital expenses, it is essential that CMS update its treatment of capital costs under the pass-through policy and no longer exclude these costs from the cost criteria.
- **Recommendation OP.6—Data and evidence for TPT payments.** CMS should be clear on evidence and data required to include an AI/software solution as providing substantial clinical improvement under the TPT. Specifically, CMS should provide guidance on how real-world evidence can be used to qualify for TPT.

MEDICARE PHYSICIAN FEE SCHEDULE

Payment for services provided by physicians and other health professionals to treat Medicare beneficiaries are established under the Medicare Physician Fee Schedule (MPFS), which uses codes to report services delivered for payment purposes.[64] Medicare mostly uses HCPCS Level I codes—which generally correspond to Category I CPT codes—to describe physician services and payment rates in the MPFS. Physicians may also submit claims for HCPCS Level III codes (Category III CPT codes) for newer procedures or technologies, although these are not usually paid for by Medicare.

The use of AI/software for the provision of those services can be incorporated into the MPFS either through the establishment of new codes or through the revaluation of current codes. Medicare establishes the payment rates for the various codes by estimating the resources used in furnishing the service to a typical Medicare patient. CMS annually determines the payment rate for services and procedures associated with a HCPCS code based on evaluating three factors: (1) the clinician work required to provide the service, (2) the practice expenses associated with the service, and (3) professional liability insurance (PLI) costs.[65]

Practice expense. For AI/software tools that do not have their own code, appropriate valuation of the practice expense component will likely have the most impact on determining whether payment sufficiently covers the costs of new technologies. Practice expense is divided into two parts: direct practice expense and indirect practice expense. Direct practice expense includes things such as nonphysician clinical labor, disposable medical supplies, and medical equipment that are typically used to provide a service to a specific patient. Indirect practice expense encompasses things such as office administration, rent, and other forms of overhead that cannot be attributed to any specific service. AI/software are often captured as part of the indirect practice expenses currently, which may undervalue them in delivery of specific services. Complicating the issue of direct and indirect expenses is the variability in costs across AI/software solutions, given the unique costs for collecting data, conducting analyses that require significant computing power, maintaining and updating systems, and engaging in research and development to provide innovative solutions.

RAND recently released a CMS-funded report on practice expense data collection and methodology.[66] The report noted that some services such as those using AI/software, may not be appropriately accounted for under the current methodology. CMS has held town halls on ways to address potential improvements to the methodologies establishing practice expense, including a town hall to obtain stakeholder perspectives on these issues.[67]

RECENT CHANGES BY CMS

While CMS grapples with the larger conceptual policy issues of how best to code, cover, and pay for AI/software in MPFS, the Agency has also made several coding, coverage, and payment decisions which may help to accommodate the growth of AI/software used by physicians in Medicare.

- **Coverage and payment for autonomous AI code.** CMS established a national payment for a stand-alone autonomous AI service (CPT code 92229) Remote Imaging of the Retina to Screen for Retinal Diseases.
- **Remote patient monitoring (RPM) codes.** Since 2019, CMS has paid for a series of RPM services for physiologic parameters, which include payments for initial set-up and patient education (CPT code 99453), device supply with data collection (CPT code 99454), time-based treatment management services based on remote patient monitoring (CPT codes 99457 and 99458), as well as collection and interpretation of physiologic data transmitted by the patient (CPT code 99091) (payment for CPT code 99091 began in 2018).
- **Remote therapeutic monitoring (RTM) codes.** CMS established payment for a series of RTM codes in 2022 and continued to try to expand use of these codes in 2023 by allowing broader supervision requirements. While initially for musculoskeletal or respiratory conditions, the CPT Editorial Panel edited the descriptors for the RTM codes to also include Cognitive Behavioral Therapy Monitoring beginning on January 1, 2023.

KEY ISSUES FOR MPFS

- **RPM/RTM limitations.** Even with the establishment of new codes, there is a lack of clarity on how the RPM/RTM codes may apply to AI/software and if they cover the full range of clinical solutions provided by AI/software. For example, RPM codes do not capture the growing complexity and multitude of information that can be reported to physicians. Within the RPM category, some devices collect and analyze a single physiologic signal, while others collect multiple signals or provide additional analytic information. It may not be appropriate to assign the same payment to these varied solutions.

  The RTM category codes do not describe all of therapeutic areas or the digital devices grounded in clinical evidence that are reasonable and necessary for the treatment of conditions that are common in the Medicare population. These inconsistencies result in some types of technology—such as many therapeutic digital technologies—not being described by the existing RTM codes and therefore limiting access to care to these innovative technologies. As a result, it is likely that a growing number of AI/software solutions will need to be considered on a case-by-case basis for separate payment as unique services.

- **Valuing AI/software.** Currently CMS does not include the full range of AI/software costs in the development of its payment rates for AI/software technology. The unique costs for collecting data, conducting analyses that require significant computing power, maintaining and updating systems (including cybersecurity), and engaging in research and development to provide innovative solutions are not included. Further AI/software is often considered an indirect expense, even if it is used for a service attributed to a specific patient.
- **"NTAP" for the MPFS.** Unlike the IPPS benefit, MPFS does not include a short-term payment adjustment for new technologies that may have higher costs but provide substantial clinical benefits for patients. This may limit advances in standards of care provided in physician offices—impacting quality and health care outcomes for Medicare beneficiaries, and also

potentially increasing health system costs. Such a policy change will require Congressional action.

- **Digital therapeutics.** Digital therapeutics are prescription digital therapies which may offer patients, in certain instances, a non-drug treatment option for a variety of conditions including sleep disorders, substance use disorders and other conditions. Although RTM codes may support use of some of these devices, they likely do not cover the range of digital therapeutics available and there is concern that payment levels will be too low to support coverage of digital therapeutics. This issue is also addressed under DMEPOS.

Exhibit 16. Recommendations to Address AI/software in MPFS

- **Recommendation PFS.1—Accurate consideration of costs.** CMS should factor the full range of AI/software costs into its payment rates including the unique costs for collecting data, conducting analyses that require significant computing power, and maintaining and updating systems (including cybersecurity).
- **Recommendation PFS.2—Direct practice expense.** CMS should consider AI/software solutions as direct practice expense—not indirect—when the AI/software services are associated with an individual patient's care. Physician work should be evaluated separately, as different AI/software solutions may impact it differently. CMS should model and make public different options for incorporating AI/software as direct practice expense for stakeholder input, including any redistributional impacts.
- **Recommendation PFS.3—Create "NTAP" in MPFS.** CMS could consider working with the Congress to establish a time-limited and non-budget-neutral add-on or incentive payment to be included in direct practice expense for new high-cost technologies that offer substantial clinical improvements, parallel to the NTAP in IPPS. This recommendation would provide an interim solution to address the larger issue of pricing and payments for new technologies including AI/software solutions under the MPFS.
- **Recommendation PFS.4—Expand RPM/RTM.** CMS should recognize that not all RPM solutions have the same expense, particularly for devices that collect and analyze multiple physiological signals. Additionally, the RTM code is too limited and other conditions could be relevant for therapeutic monitoring (i.e., cardiology or heart failure). Currently the codes for RPM/RTM pay a single rate for all monitoring devices and information. This does not reflect the variety of technologies and analyses that may be available under remote monitoring.
- **Recommendation PFS.5—New quality metrics.** CMS should consider encouraging providers to use appropriate AI/software technologies by incorporating AI/software into current quality measures (where clinically consistent) and adding quality measures related to use and adoption of AI in the practice improvement activity under Medicare's Merit-based Incentive Payment System (MIPS).

Exhibit 16 Continued

- **Recommendation PFS.6—Digital therapeutics.** CMS should clarify the criteria for coverage of digital therapeutics as a direct practice expense under MPFS. This includes further guidance on their use under the RTM codes, especially for cognitive behavioral therapies, as well as defining when new codes should be developed for the digital therapeutic AI/software product and related physician work.

Exhibit 17. Medicare Lacks a Clear Approach to Coverage of Digital Therapeutics

To date, CMS has been unclear about the path to coverage and payment in Medicare for digital therapeutics. Although these devices are FDA cleared for patient use, the lack of a coverage pathway means Medicare patients do not have access to these new treatments for conditions that may include mental health, pain management, respiratory and sleep issues, gait training, as well as other conditions.

- CMS has limited the use of the DME benefit as a coverage pathway for digital therapeutics that do not have corresponding equipment or hardware. Despite this decision, in some cases digital therapeutic devices could meet the regulatory criteria for coverage in DME. While making this negative coverage decision, CMS has also recognized the need for billing codes for these treatment options and granted HCPCS codes so that the devices could be more easily covered by Medicaid and other payers.[68]
- Although there may be flexibility to cover digital therapeutics under the MPFS, CMS has not clearly defined how these devices will be incorporated or assigned codes; nor has the Agency developed a payment methodology in MPFS for these technologies.
- Coverage is further limited in Medicare because these therapeutics, prescribed by physicians for use in patient homes, are also not eligible for coverage under the Medicare prescription drug benefit program (Part D). The Medicare Part D statute limits this benefit to coverage of drugs, biologics, vaccines and insulin syringes and smoking cessation drugs.[69]

Commercial plans and some Medicaid programs have recently moved forward to offer access to these new therapies either through establishing prescription therapeutic formularies defining coverage parameters or covering them as part of the medical benefit.

INDEPENDENT DIAGNOSTIC TESTING FACILITIES

IDTFs are a unique entity paid under the MPFS. These facilities provide diagnostic information and services to physicians outside of physician offices. Increasingly IDTFs rely on electronic information,

software and algorithms to support their work. They also face distinct challenges for payment of AI/software under the MPFS. **Exhibit 18** further explains Medicare's IDTF policy.

KEY ISSUES FOR IDTFs

- **IDTF costs are inadequately addressed.** IDTF costs are not sufficiently represented in the methodology for CMS to establish practice expenses because of reliance on the Physician Practice Information (PPI) survey as a proxy. The IDTF model is not represented in the survey, which primarily includes physicians and selected nonphysician practitioners. Instead, IDTF costs are represented by a blend of supplemental survey information from the National Coalition of Quality Diagnostic Imaging Services and the American College of Radiology. However, radiology and diagnostic imaging services represent only a portion of the IDTF market, which also includes cardiac monitoring and other services. Therefore the costs of these services are not adequately reflected.
- **IDTF payment undervalues the AI/software and service components.** Currently more information is needed to appropriately identify and pay for costs for AI/software used by IDTFs. CMS should consider expanding the IDTF functions that are reimbursed to include additional analytic services for testing with AI/software.
- **Need for greater differentiation among IDTFs and their functions.** There are different types of IDTFs with significant differentiation in model type. These differences also lead to differences in costs that are not reflected in the payments to these facilities.

Exhibit 18. IDTFs in Medicare

An IDTF is a type of Medicare provider (suppliers of diagnostic tests) that provides diagnostic information and services and is independent of a physician's office or hospital. IDTFs were established through regulations and came into existence in 1998.[70] An IDTF may be a fixed location, a mobile entity, or an individual nonphysician practitioner.[71] Importantly, there are three IDTF segmented markets with different cost structures which include:

- Radiology imaging services,
- Mobile units, and
- Remote cardiac monitoring services, such as extended or long-term electrocardiography (ECG) services.

In IDTFs, licensed or certified nonphysician technicians perform diagnostic tests under physician supervision.[72] CMS pays the IDTF based on payment rates established under the MPFS. For Medicare payment, CMS requires that the IDTF services be reasonable and necessary, ordered by a physician, and sufficiently documented.[73]

CMS sets requirements for IDTFs, including enrollment under Medicare Part B. All IDTF nonphysician personnel/technicians must be certified either through state licensure or certification by a national credentialing body and must be qualified to perform the types of tests for which the IDTF has enrolled. IDTFs must also meet various performance standards.[74, 75]

Exhibit 19. Recommendations to Address AI/software for IDTFs

- **Recommendation IDTF.1—Improve cost data collection for IDTFs.** CMS should create a new survey tool for use with IDTFs, including long-term ECG providers, to better assess costs associated with AI/software. The new survey tool will need to include both direct costs and indirect costs with specific questions that focus on AI/software use and costs for IDTFs. The survey tool should also address various types of IDTFs. The survey should include both initial start-up and ongoing maintenance costs for IDTF providers.
- **Recommendation IDTF.2—Inclusion of AI/software in IDTFs.** CMS should evaluate whether the IDTF approach of supporting third party evaluation of data collected remotely should be expanded to include the provision of AI/software tools as a covered function and receipt of an add-on payment to reflect these costs.
- **Recommendation IDTF.3—Review costs across IDTF models.** CMS should evaluate whether the IDTF payments fully account for any differences in costs for AI/software associated with different models of IDTFs, particularly additional costs for AI/software that may be incurred by manufacturers that are also IDTF providers.

DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS AND SUPPLIES

Some equipment used in the home under the DMEPOS benefit may incorporate AI/software. Further, new technologies, equipment, or devices used by patients in their homes may offer potential care and treatment opportunities that are currently not recognized by CMS under these benefit categories but should be to ensure that beneficiaries receive innovative care and treatments. Moving forward CMS will need to evaluate and clarify the scope of coverage for AI/software solutions under DMEPOS.

RECENT CHANGES BY CMS

- **The definition of DME and HCPCS coding.** CMS holds public meetings two times a year to hear and review information regarding specific HCPCS coding requests for new products, supplies, and services that are non-drug, non-biologics. Over the last few years, CMS has heard applications for a variety of technologies that incorporate software into equipment or devices or that rely on algorithms to improve treatments or even deliver treatments.[76, 77, 78] However, in decisions on applications reviewed at these meetings, CMS has demonstrated reticence to cover many new technologies or to value the software components. In particular, CMS often decides that the software does not meet the requirements for DMEPOS unless they also include equipment that meets the traditional definition of DME.

- **No clear DME coverage of digital therapeutics.** In February 2022, CMS issued a new HCPCS Level II code in connection with an application from Pear Therapeutics for a prescription digital therapy device.[79] The new CPT code, A9291, had the descriptor, "Prescription digital behavioral therapy, FDA cleared, per course of treatment." However, CMS limited the code's application to non-Medicare payers.[80] In June 2022, CMS decided that these devices should not be covered under the DME benefit.[81]
- **Coverage of virtual reality device with equipment.** Recently, CMS finalized a decision to cover a virtual reality (VR) device that offers treatment for lower back pain.[82] RelieVRx was granted FDA breakthrough status for the first de novo FDA authorized immersive VR medical device for home use that is indicated for the treatment of chronic low back pain. While the technology was designated as SaMD, the technology included other durable equipment allowing it to meet DME benefit category requirements. The technology was distinguished from other SaMD, such as recent digital therapeutics where CMS concluded the "devices consist solely of" SaMD, and did not cover them.[83]
- **Expanded coverage of CGM devices.** In 2021, CMS finalized its proposal to expand coverage of continuous glucose monitoring (CGM) devices.[84] Coverage of CGM devices as DME had previously been limited to those established as "therapeutic" by a 2017 CMS Ruling. The ruling distinguished these from "adjunctive" devices where the CGM did not replace a blood glucose monitor for making diabetes treatment decisions.[85] In the 2021 CMS final rule, however, CMS expanded coverage to adjunctive CGM and also clarified coverage based on the use of insulin pumps that also function as a CGM monitor or receiver.
- **Smart phones/home computing devices.** Another issue creating challenges is that CMS does not cover software or algorithms that can be run on smartphones or other home computing devices. CMS has determined that they do not meet the DME benefit requirements of being used solely for a medical purpose and are also useful to an individual in the absence of an illness or injury. However, CGM beneficiaries may use devices such as smartphones, tablets, or other similar devices as long as they are used secondary to a primary covered DME receiver.[86]

KEY ISSUES FOR DMEPOS

- **Flexibility needed for smart devices.** DMEPOS equipment may include applications that can be used by patients on their home computing technology or smart phones. Greater flexibility is needed to facilitate the use of these devices by beneficiaries in the home for collection of information that is related to their DMEPOS.
- **Address new functionality.** Currently, DMEPOS coverage does not have a method for addressing and paying for meaningful updates to software included in devices. Further, there is no real mechanism to pay for new AI/software functionality that may be incorporated into devices to support patient use, make them more efficient, or improve outcomes.
- **Coverage of digital therapeutics.** Currently, CMS does not interpret the regulations for DME to permit coverage of FDA cleared digital therapies in the home without a corresponding piece

of equipment or hardware. The recent decision that VR therapy met the definition was based on the integration of the software into a headset. However, other therapies that are SaMD and might otherwise meet CMS criteria for DME are not considered to be covered under this benefit category. CMS should clarify this policy but also reconsider whether their regulatory definition for DME should be expanded to cover SaMD so that Medicare beneficiaries may have greater access to these therapies.

Exhibit 20. Recommendations to Address AI/software in DMEPOS

- **Recommendation DME.1—Incorporate costs of AI/software into DMEPOS, including costs for updates.** CMS should consider how to incorporate AI/software costs associated with DMEPOS in the payment amounts for DMEPOS when software is additive to an existing technology or when it is part of new technologies. CMS could consider payment for software and its clinically meaningful updates as a "supply" in its payment methodology.
- **Recommendation DME.2—Clear path for use of smart devices for DME.** Medicare should establish a consistent and more flexible policy on the use of smart devices so that Medicare patients have access to AI and other software-based technologies that can be used on personal devices in their homes (when the personal device is not supplied by the manufacturer).
- **Recommendation DME.3—Clarity on coverage for SaMD and digital therapeutics under DME.** In the short-term, CMS should clarify the criteria for coverage of SaMD as DME, particularly any requirements regarding associated equipment that might be necessary for coverage. As part of this guidance, CMS should specifically address digital therapeutics that are FDA cleared SaMD and provide treatments for use in the home. In the longer term, CMS should recognize that SaMD can be DME, even when presented without associated equipment, for use on a personal smart device.

Exhibit 21. AI/software within the Clinical Laboratory Fee Schedule

Increasingly, AI/software solutions are being incorporated into diagnostic capabilities. This includes advances in the area of clinical laboratories, which test biological specimens to provide useful information that guides patients' diagnoses, treatment, and prognoses. AI/software solutions in the form of advanced algorithms can predict the likelihood of a disease, such as cancer.

Medicare pays for laboratory services across settings of care, but the most prominent payment system is the clinical laboratory fee schedule.[87] In addition to routine blood and urine tests, the fee schedule includes payment rates for tests classified under the Multianalyte Assays

Exhibit 21 Continued

with Algorithmic Analyses (MAAAs) and Proprietary Laboratory Analyses (PLA) code sets. The MAAAs look across biomarkers to assess "the activity of a given disease or a patient's risk of a particular disease"[88] and are identified by CPT codes that specify items such as the disease type, the specimen type and materials analyzed, the methodology used, and the report generated, which could include a probability index or risk score. The PLA code set was developed in response to the Protecting Access to Medicare Act of 2014 (PAMA) and are alphanumeric codes that include a wide range of tests, including those utilizing algorithms. Once a CPT code has been obtained, Medicare adds the test to the clinical laboratory fee schedule and sets the payment rate.

In many cases, payment for MAAAs shows recognition of the value of AI/software in the clinical laboratory space, but new innovations will likely prompt the need for additional modernization of Medicare coverage and payment in this space.

MEDICARE ADVANTAGE PLANS AND ALTERNATIVE PAYMENT MODELS

In addition to the FFS payment systems in Traditional Medicare, beneficiaries may also receive benefits in MA plans or APMs. These programs rely on the coverage and payment decisions established under Traditional Medicare but may have additional flexibilities or different payment structures that could incentivize the use of new technologies.

MEDICARE ADVANTAGE

MA plans cover a growing share of total Medicare beneficiaries and in 2023, 50 percent of Medicare beneficiaries were enrolled in MA.[89] In general, MA must cover all of the items and services available under Medicare Parts A and B and usually follow Traditional Medicare's coverage determinations, including for AI/software. However, MA plans also have flexibility for coverage not available in Traditional Medicare. These include provisions to use telehealth and supplemental benefits, which may include items and services that Traditional Medicare does not cover.

- **Telehealth flexibilities.** MA plans are required to offer the same telehealth services that are covered in Traditional Medicare. Changes made under the Bipartisan Budget Act of 2018 allowed MA to expand telehealth benefits. CMS implemented regulations to allow telehealth services to be provided as basic benefits rather than supplemental benefits beginning in 2020.[90] Additionally, during the COVID-19 pandemic, plans expanded use of telehealth, in part because

under the public health emergency CMS created flexibilities to waive or reduce cost sharing for telehealth services.[91]

- **Supplemental benefits.** MA plans may also offer additional benefits not covered by Medicare Parts A, B, or D, such as dental and vision coverage. While such benefits were originally required to be primarily health related, CMS and the Congress have expanded the types of benefits offered allowing plans to tailor to certain populations of beneficiaries with chronic conditions (**Exhibit 21**).

Exhibit 22. Medicare Advantage Supplemental Benefits

Traditional Supplemental Benefits— Primarily Health Related	Expanded Supplemental Benefits— Primarily Health-Related Benefits (Since 2019)	Special Supplemental Benefits for the Chronically Ill (Since 2020)
• Vision • Dental • Hearing • Fitness • Over the counter benefits • Limited additional services like transportation to medical appointments or meals following inpatient stays	• Traditional supplemental benefits • Expansions of additional services like meals • New services like adult day care, community-based services, and caregiver supports	• Complementary therapies • Pest control • Food and produce • Meals • Non-medical transportation • Structural home modification • Social needs benefits • Indoor air quality equipment and services • Transitional supports (e.g., rent, utilities)

Source: Adapted from Commonwealth Fund. (2021, February 10). Medicare Advantage Plans Offering Expanded Supplemental Benefits: A Look at Availability and Enrollment.

KEY ISSUES FOR MA

- **Data and evidence to support coverage.** Although opportunities exist to use new technologies, there are still limitations to uptake as MA plans generally follow Traditional Medicare's decisions on coverage. Further, MA often requires additional data to support coverage of AI/software, including evidence/data to show that use will be cost-effective.
- **Demonstrating impact on costs and quality.** MA plans may request data on demonstrated effectiveness, quality of care, or health outcomes before supporting use of new AI/software technologies. These requirements may be hard to meet for new technologies like AI/software applications. Additionally, the specific requirements for coverage may vary by plan.

Exhibit 23. Recommendations to Address AI/software in MA

- **Recommendation MA.1— CMS guidance.** CMS should work with plans to verify that they incorporate AI/software consistent with Traditional Medicare coverage policies.
- **Recommendation MA.2—Encourage use of AI/software by MA.** CMS should incentivize MA plans to provide and deploy new AI/software-based technologies by issuing guidance addressing the potential of their inclusion in supplemental benefits to improve quality and decrease costs, including for specific populations and conditions.
- **Recommendation MA.3—Digital therapeutics and supplemental benefits.** CMS should clarify that MA plans may include FDA cleared digital therapeutics as supplemental benefits either as primarily health related or as special supplemental benefits for chronically ill patients.

ALTERNATIVE PAYMENT MODELS

The Center for Medicare and Medicaid Innovation (Innovation Center) tests new payment and health care delivery models. In selecting models for testing, factors may be considered including "whether the model utilizes technology, such as electronic health records and patient-based remote monitoring systems, to coordinate care over time and across settings."[92]

To date, APMs have been developed to target specific clinical conditions, care episodes, or populations, as well as to implement broader, value-based programs. Because APMs give participating providers greater flexibility and incentives to improve patient care and outcomes, and to reduce costs, AI/software technologies that support these goals may be more readily implemented or used in models.

RECENT CHANGES BY CMS

- **CMS AI Health Outcomes Challenge.** In 2019, CMS launched the AI Health Outcomes Challenge.[93] The competition encouraged development of AI/deep learning methodologies that could predict health outcomes for Medicare beneficiaries (e.g., unplanned hospital and skilled nursing facilities admissions, adverse events within 30-days, and 12-month mortality) and then develop approaches to explain these AI solutions to clinicians and patients in a way that supports improvements in quality of care. The goal was to identify potential uses in Innovation Center initiatives. The three-stage competition, implemented in partnership with the American Academy of Family Physicians and Arnold Ventures, awarded prize funding at each phase and

announced ClosedLoop.ai as the winner and Geisinger as the runner-up in April 2021. Following the challenge, the Innovation Center acknowledged the potential to leverage AI to design and implement models, including tools to help support clinicians.[94]

- **Innovation Center strategic plan and refresh.** In October 2021, CMS released a white paper, "Driving Health System Transformation - A Strategy for the CMS Innovation Center's Second Decade."[95] The Innovation Center's refreshed strategy includes five objectives: 1) Drive Accountable Care, 2) Advance Health Equity, 3) Support Innovation, 4) Address Affordability, and 5) Partner to Achieve System Transformation. It also identified the following as areas to advance the Innovation Center's on-going strategy:
  - Development of multi-payer alignment across payers,
  - Support for patient-centered care delivery, including in the home and community,
  - Building on accountable care organizations (ACOs) and advanced primary care models,
  - Promoting equity and reaching underserved populations, and
  - Testing new flexibilities and developing new tools and approaches to support provider participation.

  In November 2022, CMS released an update on the implementation of the Innovation Center's refreshed strategy.[96, 97] Among other priorities, the Innovation Center intends to support care innovation by leveraging supports such as data and technology to advance health system transformation and meaningfully integrate specialty care into models.
- **Evolving strategy.** The one-year update to the Innovation Center's strategy refresh laid out a timeline for models and initiatives through 2029. While it has emphasized population-based total cost of care models, the Innovation Center has acknowledged the importance of and continued work on bundled payments and models that integrate specialty care. The anticipated model indicates there may be new opportunities to integrate technology into testing of care delivery and payment approaches.

KEY ISSUES FOR APMS

- **Explore inclusion of AI/software in models.** Models often do not provide clear incentives for incorporation of AI/software to support care. These incentives could include linkages to quality measures that are used to evaluate performance and payment. Temporary carve-outs or upfront infrastructure payments for technology investment costs during a testing period could also be included in model design.
- **Review opportunities to support population health .** Given a focus on population-health, technologies that may not be directly reimbursable under Traditional Medicare may have greater application and use and could be incorporated into population-based APMs.
- **Leverage learnings from the AI Health Outcomes Challenge.** The Innovation Center could incorporate AI/software and lessons learned from the AI Health Outcomes Challenge into model design and testing.

Exhibit 24. Recommendations to Address AI/software in APMs

- **Recommendation APM.1—Use and test AI/software in APMs.** CMS should incentivize the use and testing of digital health technologies—including AI/software enhancements—in APMs through the use of quality measures, bonus payments, or technical assistance to support implementation of technologies. Models for potential testing include future or existing bundled payment initiatives such as the Bundled Payments for Care Improvement (BPCI) Advanced model, Comprehensive Care for Joint Replacement (CJR) model, or "Hospitals at Home" program. Further, total cost of care models, like ACOs, could serve as approaches for testing the use and impact of AI/software on quality, patient outcomes, and health care costs.
- **Recommendation APM.2 – Build on AI Challenge to leverage AI/software to support APM goals.** CMS should continue the work started with the AI Health Outcomes Challenge to identify and test AI/software that can support patient-centered care and model goals related to care delivery and outcomes. This could entail integrating promising tools identified through the challenge into models or incentivizing model participants to partner with AI challenge awardees or other stakeholders that offer capabilities that could enhance care and outcomes for patients.

Appendix. Summary of Issues and Recommendations Across Medicare Benefit Categories

This Appendix presents a summary of the recommendations in Part II.

INPATIENT PROSPECTIVE PAYMENT SYSTEM

Key Issues and Recommendations to Address AI/software in IPPS

Issues and Challenges	Recommendations
MS-DRGs	
• **MS-DRG bundles.** The large bundles under IPPS mean that payment rates are the same for certain services regardless of whether the provider is using AI-enhanced products that improve quality and outcomes. This approach provides a disincentive to adopt technologies that may pose incremental costs but provide real improvement in care and health care outcomes. For example, assistive technology for surgery improves accuracy, resulting in a shorter recovery time after hospitalizations. • **Capital costs.** Many AI/software solutions include capital costs for the provider, such as integration into existing IT systems and adequate connectivity. It is not clear in IPPS whether the capital costs of implementing new technologies are sufficiently reflected in the related elements of the payment system, such as the annual updates to the MS-DRG relative weights and the per-case capital payments. This is because of the complex mechanisms used to update these factors and the time lag for the data used.	**Recommendation IP.1—Accurately reflect costs of AI/software when updating and reweighting MS-DRGs.** CMS should review its processes for updating and reweighting MS-DRGs to ensure more complete, accurate, and timely incorporation of costs associated with AI/software technologies. • **Methodology for updating MS-DRGs.** CMS should explain how AI/software costs are currently incorporated into MS-DRGs, including specific examples of how costs for these technologies are captured when MS-DRGs are updated and reweighted and including any possible barriers. CMS should also consider any needed improvements, which could include changes to the cost report to better capture these specific costs. • **Capital costs.** CMS should provide greater transparency on how hospitals' capital costs associated with AI/software are reflected in its updates to the relative weights and the IPPS capital payments. CMS should assess whether the hospital cost report and capital market basket adequately capture the capital costs of new

Issues and Challenges	Recommendations

MS-DRGs

- **Delayed recognition of costs.** The methodology for setting relative weights relies on analysis of historic claims and cost reports. Therefore, the IPPS does not recognize the costs of new AI/software solutions incorporated into a MS-DRG until after technologies have been purchased and the associated costs are reflected in the relative weights. The only exception is when AI/software solutions qualify for the inpatient NTAP.

technology investments.

- **Timeliness of reweighting.** CMS should evaluate the extent to which reweighting of MS-DRGs adequately incorporates the costs of AI/software, especially for technologies that transition out of NTAP status.

NTAP

- **Addressing cost of AI/software in NTAP.** Even with NTAP status, the add-on payment does not cover the full cost of the technology and requires the hospital to experience a loss when using a new technology, disincentivizing the adoption of technologies that improve patient care.
- **NTAP cost data.** More data on the costs of using AI/software need to be captured by providers and reported to CMS during the period a technology is eligible for NTAP. This would allow for better reflection of costs when the technology loses its NTAP status and CMS must incorporate its costs into the MS-DRGs weights. Specifically, more information is needed about the capital and operating costs associated with AI/software under NTAP.
- **Post-NTAP status.** The first AI/software items are now losing their NTAP status and being incorporated into base MS-DRG payments. Given the newness of NTAP payments for AI/software, and potential limitations in hospital coding of use, it is unclear if CMS has sufficient data to appropriately account for the costs of AI/software after the NTAP status expires. In addition, it is unclear how the reweighting of the MS-DRGs accounts for situations when a screening diagnostic technology approved for NTAP results in a negative test.

Recommendation IP.2—Strengthen the NTAP to include AI/software technologies. CMS should review its policies to accurately incorporate AI/software in the NTAP.

- **Recognize full array of costs.** CMS should ensure that its consideration of AI/software solutions under the NTAP recognizes the full suite of costs associated with AI/software incurred by providers and manufacturers, including unique costs for collecting data, conducting analyses that require significant computing power, and maintaining and updating systems (including cybersecurity). Further, CMS should consider how capital costs are included in the NTAP.
- **Improve provider cost data on NTAP.** CMS should include requirements for providers that benefit from NTAP to collect data on the specific costs incurred to use a technology, including both subscription costs (as appropriate) and related capital and operating expenses. This would ensure that base MS-DRG payments adequately account for the costs of AI/software once NTAP status has ended.
- **Clarify evidence requirements.** CMS should provide guidance on how real-world evidence can be used to meet the NTAP criteria (separate from the types of evidence enumerated in 42 C.F.R. § 412.87).

OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

Key Issues and Recommendations to Address AI/software in OPPS

Issues and Challenges	Recommendations

APCs, SaaS, New Technology APCs

- **Separately payable codes.** In addition to the comprehensive APCs, CMS pays separately for certain items and services, such as inter-ocular lenses (IOLs), corneal tissue acquisition costs, blood and blood products, and drugs and biologics whose costs exceed a threshold ($130 per day in 2022). Recently, CMS has also paid separately for certain new technologies like HeartFlow (a non-invasive diagnostic test to identify the impact that blockages have on blood flow to the heart) and in the 2023 final rule CMS approved other Software as a Service (SaaS) technology (LiverMultiScan, Optellum) to be paid as an add-on if done at same time as an imagining procedure or separately if done at later time. CMS finalized its proposal to accurately capture costs. It is positive that CMS is making separate payments for add-on codes as an exception to its longstanding OPPS packaging policy; this will more appropriately reflect such costs in the OPPS.
- **RFI on paying for SaaS under OPPS.** It is significant and positive that CMS included a request for information (RFI) concerning payment for SaaS in its CY 2023 OPPS Proposed Rule (**Exhibit 14**). As the use of SaaS increases, incorporating stakeholder perspectives on appropriately covering these services is a step in the right direction. However, CMS should carefully consider the options presented to ensure the most flexible approach to payment. As CMS continues to develop these policies, the Agency should clarify distinctions in technologies and make

Recommendation OP.1—Adequate consideration of costs in comprehensive APCs. CMS should factor the full range of AI/software costs into its payment rates/bundles including unique costs for collecting data, conducting analyses that require significant computing power, and maintaining and updating systems (including cybersecurity). CMS should include the costs for updates to technologies over time (including FDA-required updates and technical updates) in determining changes in payment for separately payable or bundled codes for AI/software functions over time.

Recommendation OP.2—Modifier for incremental costs. CMS should consider a modifier to the billing code for AI/software additions to comprehensive APCs to allow the Agency to better understand the incremental costs associated with some new AI/software technologies that are not placed in a New Technology APC and do not qualify for TPT payments. The modifier will allow CMS to more accurately incorporate the associated costs into the recalibration of weights over time.

Recommendation OP.3—Unique features of SaaS. CMS should acknowledge that not all SaaS should be paid the same amount under the OPPS and review whether payment approaches for SaaS adequately account for data complexity, collection, use and updates, by:

- Separately evaluating each new technology to determine the appropriate HCPCS coding, including whether or not a potential CPT code can be used to support payment for the separate and distinct service under the OPPS.

Issues and Challenges	Recommendations
APCs, SaaS, New Technology APCs	
sure they account for the variety of SaaS and AI/software to be covered.	• Considering separately payable codes for SaaS where appropriate in circumstances where the cost of the AI/software would not be adequately covered if included in the bundled service. • If not separately payable, considering whether a service should be assigned to a higher cost APC when use of SaaS results in discrete and incremental costs. **Recommendation OP.4—AI/software in New Technology APCs.** CMS should include AI/software solutions in the New Technology APCs when the AI/software technology is the primary service provided, or a significant component of the primary service provided. This will allow the Agency to collect sufficient cost and claims data to appropriately assign the primary service, inclusive of the AI/software cost, to a permanent clinical APC.
TPTs	
• **Need to recognize full costs associated with AI/software.** The pass-through designation is limited to implantable/insertable devices that are used for one patient only. Furthermore, the criteria and methodology to qualify for TPT payments may limit its availability for novel AI/software products. These limitations include requirements for cost thresholds, establishing newness, and providing evidence for substantial clinical improvement for AI/software outside of the alternative pathway. • **Need for clarity on evidence for substantial clinical improvements for AI/software.** More guidance is needed from CMS on the data and evidence necessary for AI/software solutions to meet the TPT criteria requirements for substantial clinical improvement. CMS has not issued regulations for TPT to clarify substantial clinical improvement the way it has for NTAP.	**Recommendation OP.5—Adequate consideration of costs in TPT payments.** CMS should ensure that its consideration of AI/software solutions under the TPT payments recognizes the full suite of costs associated with AI/software, including unique costs for collecting data, conducting analyses that require significant computing power, and maintaining and updating systems (including cybersecurity). As more technologies are developed utilizing AI/software technologies that have components that qualify as capital expenses, it is essential that CMS update its treatment of capital costs under the pass-through policy and no longer exclude these costs from the cost criteria. **Recommendation OP.6—Data and evidence for TPT payments.** CMS should be clear on evidence and data required to include an AI/software solution as providing substantial clinical improvement under the TPT.

Issues and Challenges	Recommendations
TPTs	
• **FDA breakthrough designation.** While breakthrough status allows new devices to automatically meet the substantial clinical improvement criteria for TPT payments, it does not automatically address the newness criteria used in CMS policies.	Specifically, CMS should provide guidance on how real-world evidence can be used for TPT.

MEDICARE PHYSICIAN FEE SCHEDULE

Key Issues and Recommendations to Address AI/software in MPFS

Issues and Challenges	Recommendations
• **RPM/RTM limitations.** Even with the establishment of new codes, there is a lack of clarity on how the RPM/RTM codes may apply to AI/software and if they cover the full range of clinical solutions provided by AI/software. For example, RPM codes do not capture the growing complexity and multitude of information that can be reported to physicians. Within the RPM category, some devices collect and analyze a single physiologic signal, while others collect multiple signals or provide additional analytic information. It may not be appropriate to assign the same payment to these varied solutions. The RTM category codes do not describe all of therapeutic areas or the digital devices grounded in clinical evidence that are reasonable and necessary for the treatment of conditions that are common in the Medicare population. These inconsistencies result in some types of technology—such as many therapeutic digital technologies—not being described by the existing RTM codes and therefore limiting access to care to these innovative technologies. As a result, it is likely that a growing number of AI/software solutions will need to be considered on a case-by-case basis for separate payment as unique services.	**Recommendation PFS.1—Accurate consideration of costs.** CMS should factor the full range of AI/software costs into its payment rates including the unique costs for collecting data, conducting analyses that require significant computing power, and maintaining and updating systems (including cybersecurity). **Recommendation PFS.2—Direct practice expense.** CMS should consider AI/software solutions as direct practice expense—not indirect—when the AI/software services are associated with an individual patient's care. Physician work should be evaluated separately, as different AI/software solutions may impact it differently. CMS should model and make public different options for incorporating AI/software as direct practice expense for stakeholder input, including any redistributional impacts. **Recommendation PFS.3—Create "NTAP" in MPFS.** CMS could consider working with the Congress to establish a time-limited and non-budget-neutral add-on or incentive payment to be included in direct practice expense for new high-cost technologies that offer substantial clinical improvements, parallel to the NTAP in IPPS. This recommendation would provide an interim solution to address the larger issue of pricing and payments for new technologies including AI/software solutions under the MPFS.

Issues and Challenges	Recommendations
• **Valuing AI/software.** Currently CMS does not include the full range of AI/software costs in the development of its payment rates for AI/software technology. The unique costs for collecting data, conducting analyses that require significant computing power, maintaining and updating systems (including cybersecurity), and engaging in research and development to provide innovative solutions are not included. Further AI/software is only considered an indirect expense, even if it is used for a service attributed to a specific patient. • **"NTAP" for the MPFS.** Unlike the IPPS benefit, MPFS does not include a short-term payment adjustment for new technologies that may have higher costs but provide substantial clinical benefits for patients. This may limit advances in standards of care provided in physician offices—impacting quality and health care outcomes for Medicare beneficiaries, and also potentially increasing health system costs. Such a policy change will require Congressional action. • **Digital therapeutics.** Digital therapeutics are prescription digital therapies which may offer patients, in certain instances, a non-drug treatment option for a variety of conditions including sleep disorders, substance use disorders and other conditions. Although RTM codes may support use of some of these devices, they likely do not cover the range of digital therapeutics available and there is concern that payment levels will be too low to support coverage of digital therapeutics. This issue is also addressed under DMEPOS.	**Recommendation PFS.4—Expand RPM/RTM.** CMS should recognize that not all RPM solutions have the same expense, particularly for devices that collect and analyze multiple physiological signals. Additionally, the RTM code is too limited and other conditions could be relevant for therapeutic monitoring (i.e., cardiology or heart failure). Currently the codes for RPM/RTM pay a single rate for all monitoring devices and information. This does not reflect the variety of technologies and analyses that may be available under remote monitoring. **Recommendation PFS.5—New quality metrics.** CMS should consider encouraging providers to use appropriate AI/software technologies by incorporating AI/software into current quality measures (where clinically consistent) and adding quality measures related to use and adoption of AI in the practice improvement activity under Medicare's Merit-based Incentive Payment System (MIPS). **Recommendation PFS.6—Digital therapeutics.** CMS should clarify the criteria for coverage of digital therapeutics as a direct practice expense under MPFS. This includes further guidance on their use under the RTM codes, especially for cognitive behavioral therapies, as well as defining when new codes should be developed for the digital therapeutic AI/software product and related physician work.

INDEPENDENT DIAGNOSTIC TESTING FACILITIES

Key Issues and Recommendations to Address AI/software in IDTFs

Issues and Challenges	Recommendations
• **IDTF costs are inadequately addressed.** IDTF costs are not sufficiently represented in	**Recommendation IDTF.1—Improve cost data collection for IDTFs.** CMS should create a new survey

Issues and Challenges	Recommendations
the methodology for CMS to establish practice expenses because of reliance on the Physician Practice Information (PPI) survey as a proxy. The IDTF model is not represented in the survey, which primarily includes physicians and selected nonphysician practitioners. Instead, IDTF costs are represented by a blend of supplemental survey information from the National Coalition of Quality Diagnostic Imaging Services and the American College of Radiology. However, radiology and diagnostic imaging services represent only a portion of the IDTF market, which also includes cardiac monitoring and other services. Therefore the costs of these services are not adequately reflected. • **IDTF payment undervalues the AI/software and service components.** Currently more information is needed to appropriately identify and pay for costs for AI/software used by IDTFs. CMS should consider expanding the IDTF functions that are reimbursed to include additional analytic services for testing with AI/software. • **Need for greater differentiation among IDTFs and their functions.** There are different types of IDTFs with significant differentiation in model type. These differences also lead to differences in costs that are not reflected in the payments to these facilities.	tool for use with IDTFs, including long-term ECG providers, to better assess costs associated with AI/software. The new survey tool will need to include both direct costs and indirect costs with specific questions that focus on AI/software use and costs for IDTFs. The survey tool should also address various types of IDTFs. The survey should include both initial start-up and on-going cost maintenance costs for IDTF providers. **Recommendation IDTF.2—Inclusion of AI/software in IDTFs.** CMS should evaluate whether the IDTF approach of supporting third party evaluation of data collected remotely should be expanded to include the provision of AI/software tools as a covered function and receipt of an add-on payment to reflect these costs. **Recommendation IDTF.3—Review costs across IDTF models.** CMS should evaluate whether the IDTF payments fully account for any differences in costs for AI/software associated with different models of IDTFs, particularly additional costs for AI/software that may be incurred by manufacturers that are also IDTF providers.

DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS AND SUPPLIES

Key Issues and Recommendations to Address AI/software in DMEPOS

Issues and Challenges	Recommendations
• **Flexibility needed for smart devices.** DMEPOS equipment may include applications that can be used by patients on their home computing technology or smart phones. Greater flexibility is needed to facilitate the use of these devices by	**Recommendation DME.1—Incorporate costs of AI/software into DMEPOS—including costs for updates.** CMS should consider how to incorporate AI/software costs associated with DMEPOS in the payment amounts for DMEPOS when software is

Issues and Challenges	Recommendations
beneficiaries in the home for collection information that is related to their DMEPOS. • **Address new functionality.** Currently, DMEPOS coverage does not have a method for addressing and paying for meaningful updates to software included in devices. Further, there is no real mechanism to pay for new AI/software functionality that may be incorporated into devices to support patient use, make them more efficient, or improve outcomes. • **Coverage of digital therapeutics.** Currently, CMS does not interpret the regulations for DME to permit coverage of FDA cleared digital therapies in the home without a corresponding piece of equipment or hardware. The recent decision that VR therapy met the definition was based on the integration of the software into a headset. However, other therapies that are SaMD and might otherwise meet CMS criteria for DME are not considered to be covered under this benefit category. CMS should clarify this policy but also reconsider whether their regulatory definition for DME should be expanded to cover SaMD so that Medicare beneficiaries may have greater access to these therapies.	additive to an existing technology or when it is part of new technologies. CMS could consider payment for software and its clinically meaningful updates as a "supply" in its payment methodology. **Recommendation DME.2—Clear path for use of smart devices for DME.** Medicare should establish a consistent and more flexible policy on the use of smart devices so that Medicare patients have access to AI and other software-based technologies that can be used on personal devices in their homes (when the personal device is not supplied by the manufacturer). **Recommendation DME.3—Clarity on coverage for SaMD and digital therapeutics under DME.** In the short-term, CMS should clarify the criteria for coverage of SaMD as DME, particularly any requirements regarding associated equipment that might be necessary for coverage. As part of this guidance, CMS should specifically address digital therapeutics that are FDA cleared SaMD and provide treatments for use in the home. In the longer term, CMS should recognize that SaMD can be DME, even when presented without associated equipment, for use on a personal smart device.

MEDICARE ADVANTAGE

Key Issues and Recommendations to Address AI/software in MA

Issues and Challenges	Recommendations
• **Data and evidence to support coverage.** Although opportunities exist to use new technologies, there are still limitations to uptake as MA plans generally follow Traditional Medicare's decisions on coverage. Further, MA often requires additional data to support coverage of AI/software, including evidence/data to show that use will be cost-effective.	**Recommendation MA.1— CMS guidance.** CMS should work with MA plans to verify that they incorporate AI/software consistent with Traditional Medicare coverage policies. **Recommendation MA.2—Encourage use of AI/software by MA plans.** CMS should incentivize MA plans to provide and deploy new AI/software-based technologies by issuing guidance addressing the

Issues and Challenges	Recommendations
• **Demonstrating impact on costs and quality.** MA plans may request data on demonstrated effectiveness, quality of care, or health outcomes before supporting use of new AI/software technologies. These requirements may be hard to meet for new technologies like AI/software applications. Additionally, the specific requirements for coverage may vary by plan.	potential of their inclusion in supplemental benefits to improve quality and decrease costs, including for specific populations and conditions. **Recommendation MA.3—Digital therapeutics and supplemental benefits.** CMS should clarify that MA plans may include FDA cleared digital therapeutics as supplemental benefits either as primarily health related or as special supplemental benefits for chronically ill patients.

ALTERNATIVE PAYMENT MODELS

Key Issues and Recommendations to Address AI/software in APMs

Issues and Challenges	Recommendations
• **Explore inclusion of AI/software in models.** Models often do not provide clear incentives for incorporation of AI/software to support care. These incentives could include linkages to quality measures that are used to evaluate performance and payment. Temporary carve-outs or upfront infrastructure payments for technology investment costs during a testing period could also be included in model design. • **Review opportunities to support population-based health care goals.** Given a focus on population-health, technologies that may not be directly reimbursable under Traditional Medicare may have greater application and use and could be incorporated into population-based APMs. • **Leverage learnings from the AI Health Outcomes Challenge.** The Innovation Center could incorporate AI/software and lessons learned from the AI Health Outcomes Challenge into model design and testing.	**Recommendation APM.1—Use and test AI/software in APMs.** CMS should incentivize the use and testing of digital health technologies—including AI/software enhancements—in APMs through the use of quality measures, bonus payments, or technical assistance to support implementation of technologies. Models for potential testing include future or existing bundled payment initiatives such as the Bundled Payments for Care Improvement (BPCI) Advanced model, Comprehensive Care for Joint Replacement (CJR) model, or "Hospitals at Home" program. Further, total cost of care models, like ACOs, could serve as approaches for testing the use and impact of AI/software on quality, patient outcomes, and health care costs. **Recommendation APM.2 – Build on AI Challenge to leverage AI/software to support APM goals.** CMS should continue the work started with the AI Health Outcomes Challenge to identify and test AI/software that can support patient-centered care and model goals related to care delivery and outcomes. This could entail integrating promising tools identified through the challenge into models or incentivizing model participants to partner with AI challenge awardees or other stakeholders that offer capabilities that could enhance care and outcomes for patients.

Appendix. Summary of Digital Therapeutics Recommendations

Issues and Challenges	Recommendations
MPFs	
Digital therapeutics. Digital therapeutics are prescription digital therapies which may offer patients, in certain instances, a non-drug treatment option for a variety of conditions including sleep disorders, substance use disorders and other conditions. Although RTM codes may support use of some of these devices, they likely do not cover the range of digital therapeutics available and there is concern that payment levels will be too low to support coverage of digital therapeutics.	**Recommendation PFS.6—Digital therapeutics.** CMS should clarify the criteria for coverage of digital therapeutics as a direct practice expense under MPFS. This includes further guidance on their use under the RTM codes, especially for cognitive behavioral therapies, as well as defining when new codes should be developed for the digital therapeutic AI/software product and related physician work.
DMEPOS	
Coverage of digital therapeutics. Currently, CMS does not interpret the regulations for DME to permit coverage of FDA cleared digital therapies in the home without a corresponding piece of equipment or hardware. The recent decision that VR therapy met the definition was based on the integration of the software into a headset. However, other therapies that are SaMD and might otherwise meet CMS criteria for DME are not considered to be covered under this benefit category. CMS should clarify this policy but also reconsider whether their regulatory definition for DME should be expanded to cover SaMD so that Medicare beneficiaries may have greater access to these therapies.	**Recommendation DME.3—Clarity on coverage for SaMD and digital therapeutics under DME.** In the short-term, CMS should clarify the criteria for coverage of SaMD as DME, particularly any requirements regarding associated equipment that might be necessary for coverage. As part of this guidance, CMS should specifically address digital therapeutics that are FDA cleared SaMD and provide treatments for use in the home. In the longer term, CMS should recognize that SaMD can be DME, even when presented without associated equipment, for use on a personal smart device.
MA	
Data/evidence to support coverage. Although opportunities exist to use new technologies, there are	**Recommendation MA.3—Digital therapeutics and supplemental benefits.** CMS should clarify that MA

Issues and Challenges	Recommendations
MA	
still limitations to uptake as MA plans generally follow Traditional Medicare's decisions on coverage. Further, MA often requires additional data to support coverage of AI/software, including evidence/data to show that use will be cost-effective. **Demonstrating impact on costs and quality.** MA plans may request data on demonstrated effectiveness, quality of care, or health outcomes before supporting use of new AI/software technologies. These requirements may be hard to meet for new technologies like AI/software applications. Additionally, the specific requirements for coverage may vary by plan.	plans may include FDA cleared digital therapeutics as supplemental benefits either as primarily health related or as special supplemental benefits for chronically ill patients.

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51 Although CMS has established regulations at 42 C.F.R. § 412.87 to provide additional guidance that spells the types of improvement and types of evidence the agency considers when evaluating devices for the NTAP, AI/software solutions pose additional considerations that have not been specifically addressed by the

agency, such as issuing guidance on real-world evidence in coverage decisions or providing early advice to companies on evidence generation for AI/software.

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