



# Modernizing Medicare Coverage of Digital Health Technologies

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## EXECUTIVE SUMMARY

# MODERNIZING MEDICARE COVERAGE OF DIGITAL HEALTH TECHNOLOGIES

The field of digital health has opened new frontiers in care delivery and health management, and innovation continues to occur at a rapid pace. Digital health technologies are 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. As the single largest payer for health care in the U.S., Medicare can lead efforts to deploy digital health solutions to meet the challenges of improving care and reducing costs. However, current interpretation and application of Medicare regulations restrict wider coverage, use, and diffusion of these important technologies throughout the program.

The Medicare statute does not directly address coverage of digital health technologies nor does the statute specifically limit or prohibit coverage of digital health technologies within the program's benefit categories. While this report focuses on digital health technologies generally, it does not make recommendations for telehealth benefits, which do have specific statutory and regulatory coverage provisions (see Box 2.2 Coverage of Telehealth in Medicare). In the absence of an explicit benefit category or categories, digital health technologies may be eligible for reimbursement by Medicare under existing benefit pathways for either "direct" coverage and payment, or "indirect" coverage as an allowable cost of service provision. In both direct and indirect payment pathways, incentives to use the technology are dependent on adequate coverage and reimbursement policies under Medicare.

Updating Medicare's coverage pathways is necessary to accommodate advances in technologies that improve the standard of care and patient engagement. While the statutory and regulatory provisions for Medicare's benefit categories establish coverage parameters, there are regulatory opportunities under these frameworks to improve coverage of digital health technologies. Using this regulatory flexibility, the Centers for Medicare & Medicaid Services (CMS) can take necessary steps to move Medicare forward in addressing coverage and payment of digital health technologies. Furthermore, given Medicare's importance in the health care marketplace, CMS and policymakers in Congress must seize opportunities to take a leadership role in coordinating and collaborating with stakeholders.

This report focuses on ways to modernize Medicare's payment and coverage policies to capture the potential of digital health technologies used by patients, providers, health systems, and health plans. Drawing on several parallel research efforts, including analysis of regulations and interviews with experts from manufacturing companies innovating in digital health technology as well as private payers, the report outlines steps to achieve a modernized Medicare framework for coverage and payment of digital health technologies, identifies barriers in current coverage and payment policy, and offers recommendations for solutions, geared toward CMS, the U.S. Department of Health and Human Services (HHS), and Congress.

Current coverage and payment pathways, designed for traditional technologies and devices, must be adapted and updated to ensure access to digital health technologies that can improve quality and patient outcomes and help reduce the total cost of care. This report identifies key issues and opportunities for digital health technology coverage and payment within the Medicare program and makes recommendations to address those issues. The recommendations focus on recognizing the value of innovative software and applications under existing Medicare payment systems, expanding the use of remote patient monitoring (RPM) and other digital communications between patients and providers, and better linking approval and clearance of innovative and breakthrough technologies by the Food and Drug Administration (FDA) with coverage processes under Medicare.

Specifically, the report makes recommendations to improve the regulatory approach for Medicare coverage and payment of digital health technologies as follows:

- In areas where technologies could be covered directly, such as in **home and community settings**, recommendations are made to cover digital health technologies under the durable medical equipment (DME) benefit category as well as prosthetics, orthotics and their corresponding supplies. These recommendations address improving coverage of software under these categories as well as speeding coverage of devices that have achieved FDA's breakthrough designation.
- For technologies that may be indirectly covered as allowable costs within **physician, hospital inpatient and outpatient, end-stage renal disease facilities, and in post-acute care settings**, recommendations are made to update assessments of costs, review coding processes, and to better address alignment between FDA clearance and CMS coverage and payment determination processes.
- In **alternative payment models**, recommendations are made to better align incentives for the use of cost-saving technologies and for CMS to test new payment and delivery models integrating digital health technologies into model design.
- In **Medicare Advantage**, recommendations focus on encouraging the use of flexibilities health plans have in expanding access to digital health technologies.

The digital health technology industry is at an inflection point. CMS can move forward with these recommendations under current law to realize the game-changing potential of digital health technologies across health care. It will require that stakeholders and policymakers identify and address barriers to adoption and diffusion, including those relating to payment and coverage. Moving forward expeditiously will require strong leadership as well as a collaborative effort, particularly to build new strategies for diffusion of digital health technologies in the marketplace. As part of this effort:

- **CMS should review all Medicare regulations, policy guidance, and program manual instructions** to determine which changes should be made to accommodate digital health technologies.
- **CMS should apply and expand the lessons learned from the increased coverage and use of digital health technologies under the COVID-19 public health emergency waivers.** CMS should evaluate longer-term health system needs and make permanent the flexibilities that have increased coverage and payment for telehealth and RPM during the public health emergency. CMS should also consider using waivers and flexibilities to expand coverage of digital health technologies not currently covered by the Medicare program to assess their potential impact on improving access, quality, and decreasing health system costs—especially in the context of health system changes accelerated by the pandemic.
- **HHS should establish an Inter-agency Task Force** to explore policies to improve access to and coverage of digital health technologies, including coordination across federal and state agencies.
- **HHS should create a Public-Private Consortium** to support the use and diffusion of digital health technologies.

The analysis presented in this report demonstrates significant potential for regulatory modernization and opportunities to support CMS's leadership role in the health care marketplace.

To the extent existing regulatory barriers prove insurmountable, changes in legislation may be warranted to ensure that Medicare beneficiaries have timely access to state-of-the-art digital health technologies as part of clinical care. Digital health technologies offer the path forward in transforming health care delivery and management and more can and must be done to expand their use in Medicare.



# INTRODUCTION

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Digital health technologies are 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. They include devices with integrated software, mobile apps, sensors, clinical support software, as well as artificial intelligence (AI), which are powered by advanced computing science to improve patient health outcomes and health care delivery. Digital health technologies are positioned to transform care delivery with the capacity to strengthen connections between patients and providers; to facilitate care delivery in the community; and to inform diagnosis, treatment, and care management. This potential is underscored by the growth in the digital health sector. By 2017, an estimated 120,000 health-related mobile applications had been developed to support the management of clinical conditions.<sup>1</sup>

Coverage, use, and diffusion of digital health technologies will be more fully realized for patients and the health care system when Medicare modernizes its approach to coverage and payment. In Medicare, digital health technologies must qualify for coverage under a defined benefit category, which may be further constrained by regulatory requirements. To better evaluate opportunities to expand coverage of digital health technologies in the Medicare program, this report synthesizes findings from statutory and regulatory research, reviews of the health policy literature, and reported coverage challenges and experiences from interviews with manufacturers and select payers. (See: Report Methodology: Research, Literature Review, and Interviews).

Based on this research and analysis, actionable recommendations have been developed for CMS—under existing statutory authority—to improve coverage of and payment for digital health technologies. The recommendations will help promote the potential of digital health to transform care in Medicare and will better accommodate the rapid advancements of these technologies for beneficiaries (the analysis and recommendations do not focus on telehealth services). Additionally, the report includes broader recommendations intended to establish a strong infrastructure for digital health technology at CMS, across HHS agencies, and to facilitate collaborations with stakeholders to ensure regulatory frameworks can adapt and keep pace with technological advances.

The analyses and recommendations are presented in the following chapters:

- Chapter 1 describes the digital health technology landscape and outlines a framework for assessing Medicare coverage;
- Chapters 2 and 3 outline recommendations to modernize Medicare fee-for-service and Medicare Advantage (MA) regulatory policies, respectively; and
- Chapter 4 identifies the larger role Medicare can play in the health care marketplace to facilitate the diffusion of digital health technologies.

## Report Methodology: Research, Literature Review, and Interviews

The report is based on a systematic examination of the current issues that patients, providers, health systems and digital health technology manufacturers face in the uptake and diffusion of new technologies in Medicare. A combination of primary and secondary research activities informed the analysis and recommendations in the report, including:

- Interviews with 19 AdvaMed member companies engaged in innovation in the digital health industry;
- Discussions with select commercial payers on coverage and payment issues for digital health technologies;
- Literature review of peer-reviewed journal articles and policy papers on digital health coverage and payment issues in Medicare and for commercial payers;
- Research on existing Medicare benefit coverage and payment pathways including:
  - Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS),
  - Physician services,
  - Inpatient Diagnosis Related Groups (DRGs),
  - Outpatient ambulatory payment classifications (APCs),
  - Dialysis facilities for end-stage renal disease (ESRD),
  - Home health agencies (HHAs),
  - Skilled nursing facilities (SNFs),
  - Alternative payment models (APMs), and
  - Medicare Advantage (MA) plans; and
- Review of Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) processes.

Based on this methodology, issues with Medicare's current regulatory structure were identified and recommendations to modernize Medicare's policies were developed.



# 1 THE GROWTH OF DIGITAL HEALTH TECHNOLOGY AND IMPLICATIONS FOR MEDICARE

Recent years have seen a proliferation of new digital health technologies that harness patient data, including sensors; software applications (i.e. “apps”); and “smart” devices that collect, store, analyze and transmit these data to support the delivery of care. The digital health sector is forecasted to grow to as much as \$500 billion by 2026, yet its potential to transform care in Medicare is only beginning to be realized.<sup>2</sup>

This report focuses on steps CMS can take to update and modernize its regulatory framework to better realize the potential of digital health technologies in Medicare. It also proposes enhanced collaboration across stakeholders to capture the potential of digital health technologies to transform care for patients as well as care management processes for providers, health plans and health systems. This chapter:

- ▶ Describes the growth in the digital health sector and identifies implications for Medicare;
- ▶ Highlights issues in alignment between FDA and CMS, and develops recommendations to address policy gaps; and
- ▶ Presents a framework for and recommendations to improve the coverage of and payment for digital health technologies in Medicare.

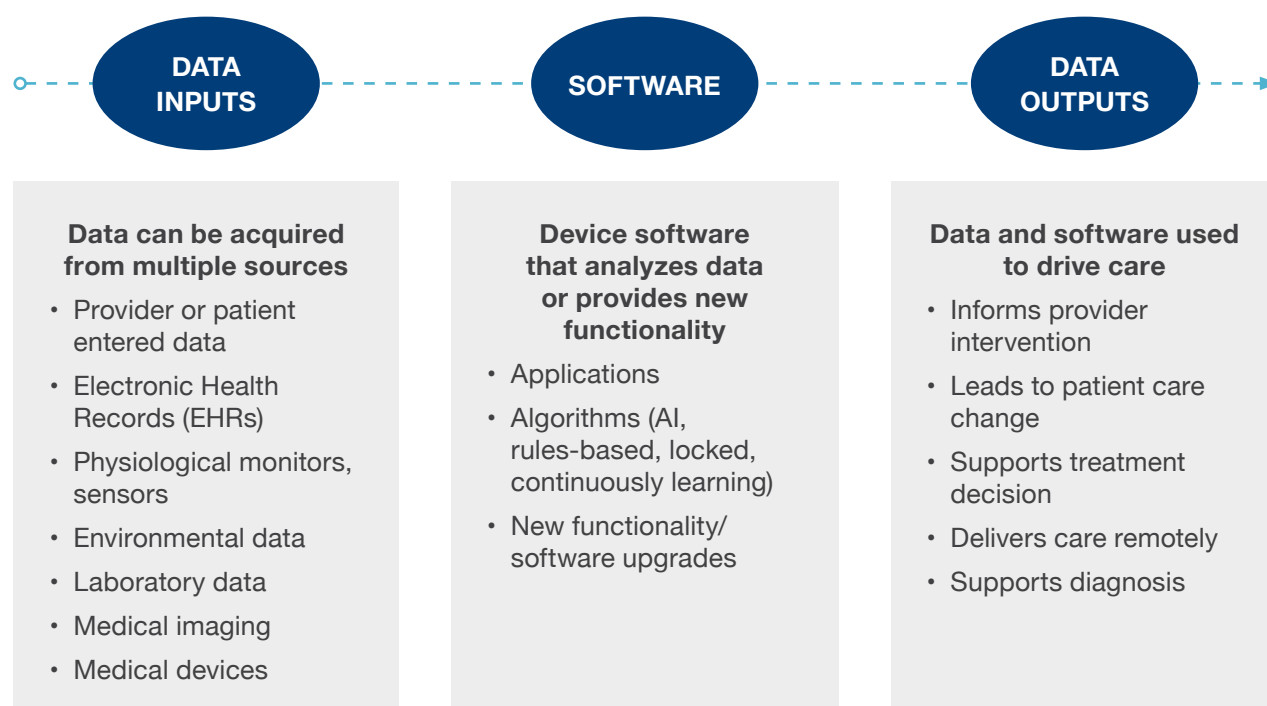
## Growth in the Digital Health Sector and Implications for Medicare

Several factors have spurred the proliferation of digital health technologies and their applications to diagnose, treat, and manage health conditions. Venture capital funding in digital health start-ups (broadly defined) has grown meaningfully from \$1.1 billion in 2011 to \$8.2 billion in 2018 and \$7.4 billion in 2019.<sup>3</sup> As of 2017, there were over 300,000 health-related mobile applications—40 percent of which were intended to support management of medical conditions.<sup>4</sup>

Some of these advances in digital health are being used to strengthen and support existing technologies, such as telehealth, where 25 percent annual growth between 2015 and 2020 built a market now valued at \$2.6 billion.<sup>5</sup> Other developments represent new and rapidly growing health sectors, such as the global market for technologies used in monitoring health conditions at home, which is expected to grow from \$17 billion in 2016 to \$48.5 billion in 2024.<sup>6</sup> And still others relate to early exploration of new ways to deliver and organize services, including decision-support technologies. The latter type of digital health advances encompasses a range of areas, including imaging using AI that incorporates and applies extensive data and new learning in real time, advancements in robotics (including applications for surgery, prosthetics, and even nurse robots) as well as virtual reality applications ranging from training to palliative care.<sup>7</sup>

Focusing on the functions that digital health technologies perform, or how they collect patient data (data inputs) and use patient data (data outputs), offers a useful framework for the assessment of how digital health technologies may impact patient care (see Figure 1.1). At the most basic level, digital health technologies acquire data, analyze the data using software, and provide information to providers or patients to drive care in a meaningful way.

**Figure 1.1. Common Elements of Digital Health Technologies**



**SOURCE:** CapView Strategies Analysis; Duke-Margolis Center for Health Policy, (2019, June 6). *Current State and Near-Term Priorities for AI-Enabled Diagnostic Support Software in Health Care*.

For patients, digital health technologies can help create a patient-centered and patient-driven health care experience, assist in making timely care more accessible, and empower patients and caregivers as active participants in their own care. For providers, digital health technologies may offer important new tools in promoting evidence-based and personalized care for patients across the health care continuum. More than 30 million Americans had a telehealth visit in 2017, while 52 percent of mobile phone users collected health-related information on their devices, and more than 25 percent of physicians used a mobile health app.<sup>8</sup>

Digital health technologies also have population health benefits by helping preserve and expand access to care and by supporting public health initiatives. Technologies can address service capacity constraints by facilitating care management in the home, reaching underserved and vulnerable populations, helping manage chronic diseases effectively, and supporting a range of public health efforts from immunization to epidemic management. Further, responses to the COVID-19 pandemic illustrate the broader potential for digital health technologies to protect and promote public and population health, and to support emergency preparedness and response efforts.<sup>9</sup>

## Digital Health Technologies in Medicare

While digital health technologies are playing a growing role in care management across markets, uptake and diffusion in Medicare is limited by CMS's regulatory policies on coverage and payment for digital health. For example, although continuous glucose monitors (CGMs) entered the marketplace in the mid-2000s and were used extensively by patients, it was not until 2017 that they were covered by CMS, despite strong evidence supporting coverage. Even so, the coverage policy does not fully address the way patients use the technology on their personal smart phones. This is an example of the gap between CMS's coverage policies and the pace of innovation, which highlights the urgency to modernize CMS's regulations to keep pace with evolving standards of care. In recent regulations, CMS has started to allow some forms of RPM to be counted as allowable expenses in payment systems for physicians and providers in hospitals, post-acute care services, and managed care plans. However, additional analysis and review of regulations and policies are needed by CMS to ensure access to clinically meaningful advancements in care.

The benefits of expanded coverage and payment of digital health technologies have recently been demonstrated in actions taken by HHS and CMS through new waiver authority in response to the COVID-19 declared public health emergency. This declaration allowed CMS to waive certain Medicare statutory and regulatory requirements, many of which expanded access to digital health services such as telehealth and remote physiological monitoring. These expansions during the COVID-19 response will offer lessons learned regarding the benefits of digital health technologies in promoting access to and management of critical health services for the future.

## FDA's Regulatory Approach to Digital Health and Implications for CMS Coverage

FDA and CMS are the primary regulatory agencies guiding approval/clearance and coverage and payment, respectively, for new medical technologies in the Medicare program. However, FDA is ahead of CMS in addressing the advances in digital health technologies, as well as in developing regulatory policies to respond to this growing sector. In FDA's "Digital Health Innovation Action Plan," the agency outlines efforts to foster innovation in the digital health sector, while protecting public health and safety.<sup>10</sup> These efforts not only highlight FDA's recognition of the growing importance of digital health technologies and their role in "driving a revolution in health care," but also the agency's acknowledgement of the need to develop an evolving regulatory framework.<sup>11</sup>

While FDA's regulatory processes for reviewing digital health technologies to assure safety and efficacy are beyond the scope of this report, there are two areas where the agency's designations and review processes may offer insights into opportunities to improve coverage of digital health technologies in Medicare. The first area is FDA's program for review of breakthrough devices and the second is the agency's evolving regulation of software and applications.

- **FDA's Breakthrough Devices Program.** The goal of FDA's Breakthrough Devices Program is to speed access to certain medical devices while still maintaining thorough and appropriate review standards. Devices with breakthrough designation are ones that offer more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions and that also meet other requirements, such as having no approved alternatives or offering significant advantages over existing approved therapies. Because breakthrough devices offer significant improvements in care or treatment for patients, FDA has prioritized efforts to ensure these are available as quickly as possible while still meeting appropriate review requirements. However, there is currently no equivalent process to ensure Medicare covers and pays for these new technologies, which would allow for prompt access by beneficiaries.<sup>12</sup>
- **FDA Regulation of Software and Medical Applications.** FDA regulates certain types of software that may be used either as a medical device—known as “Software as a Medical Device (SaMD)”—or in conjunction with a medical device—known as “Software in a Medical Device (SiMD).” The agency refers to such software collectively as “device software functions.” SaMD and SiMD may be used on mobile platforms, other general-purpose computing platforms, or in the function or control of a hardware device. If these are used on a mobile platform, they may be referred to as a “mobile medical app.” In recent years, FDA has provided guidance and examples on regulating these device software functions and is working to clarify their definitions and framework for the regulation of software.

FDA's review and approval/clearance processes for both breakthrough technologies and device software functions could be used more extensively to inform Medicare coverage policies for digital health technologies. For instance, CMS has recently created a pathway to coverage and payment for some breakthrough technologies that are high cost under the new technology add-on payment (NTAP) program in the inpatient hospital setting. CMS also created a parallel approach for high-cost technologies through the transitional pass-through payment program in outpatient hospital settings. These issues are discussed further in Chapter 2 and recommendations are made to better align CMS and FDA processes.

## Pathways for Coverage and Payment in Medicare

Despite some alignment between FDA and CMS on the designations outlined above, it is not clear how CMS incorporates FDA's evaluations of medical device functions into coverage determinations more generally, and particularly for mobile medical applications. Additionally, CMS's policies provide no structures or roadmaps for addressing digital health technologies in the path from FDA clearance to decisions of Medicare coverage and payment. As a result, pathways for Medicare coverage of and payment for digital health technology are not transparent to key stakeholders, including device manufacturers, patients, providers, health systems or health plans.

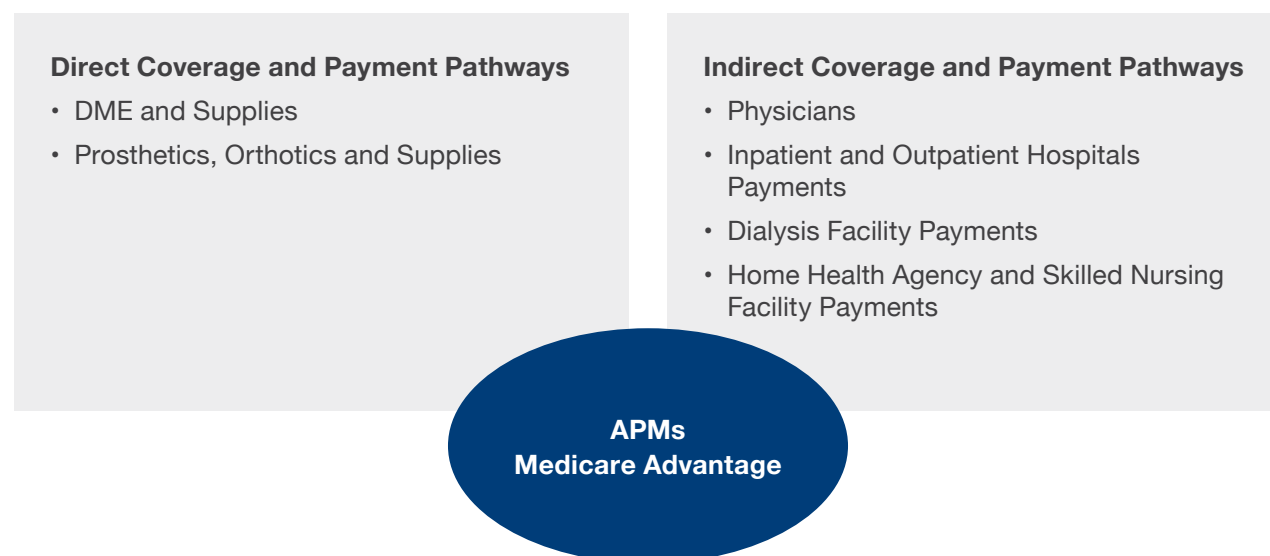
Once a digital health technology has achieved FDA approval/clearance and has met Medicare's medical necessity criteria, it may be eligible for coverage by CMS—yet, there is lack of clarity about the decision processes and regulations governing whether or not the technology will be covered. The Medicare statute neither clarifies under which benefit categories coverage could occur nor does the statute limit the coverage of digital health technologies within its benefit categories. Limitations in CMS's coverage of digital health technologies exists not in the statutory definitions of the benefit categories themselves, but rather in CMS's implementation of the statute through its regulations. CMS's interpretation and implementation of the regulations—which have not been systematically updated or modernized to address digital health technologies—have adversely impacted access and coverage.

In the absence of an explicit benefit category or categories, digital health technologies may be eligible for reimbursement by Medicare either under existing benefit pathways for “direct” coverage and payment, or through “indirect” coverage pathways as an allowable cost of service provision (see Figure 1.2). Through direct coverage, Medicare pays a supplier or manufacturer for a covered item or device that is used by a beneficiary. An example of this type of coverage is the recent Medicare decision to cover CGM systems—which allow patients to self-monitor diabetes using a digital health technology—as a DME benefit.

With indirect coverage, providers are not paid directly for the digital health technology itself, but rather the cost of the technology is included in the bundle of allowable items in the payment system for the benefit. As technologies emerge in the marketplace, diffusion may occur as providers seek to make advancements in patient care; however, to be included in the payment methodology for a benefit category, the digital health technology must be defined by Medicare as an allowable cost of service provision.

Examples of indirect coverage include RPM platforms used by physicians to monitor patients with chronic conditions that are included as an expense in the physician fee schedule. In hospitals, nursing homes, home health, dialysis facilities, and in managed care plans, digital health technologies that facilitate care management and care coordination are reimbursed through prospective payment bundles. Within Medicare Advantage payment rates paid to the plan on behalf of a beneficiary encompass direct and indirectly covered technologies. Alternative payment models (APMs) may also serve to promote diffusion of digital health technologies through the use of quality incentives, and flexibilities in model design. APMs can create new incentives to improve care and efficiency, waive restrictions on coverage and payment for technologies (e.g., telehealth), and give providers and health systems greater flexibility in care management.

**Figure 1.2 Examples of Medicare Direct and Indirect Coverage and Payment Pathways**



**SOURCE:** CapView Strategies Analysis

The growth in digital health technology spans new advances from remote sensors to monitor patient health status, to digital therapies, to robotics, and to AI that supports diagnosis and treatment. Because these are new with no precedent of coverage for comparable technologies, they raise questions about which Medicare coverage and payment pathways are most applicable. However, the assessment of which pathways—direct or indirect—are appropriate for coverage can be determined by asking a series of questions about the technology including: 1) in which setting(s) is the technology used, 2) who is the user, and 3) how Medicare regulatory requirements are being addressed (see Table 1.1).

These questions are addressed in Chapters 2 and 3 and guide the proposed recommendations to improve Medicare regulatory policies.



**Table 1.1. Key Questions on Digital Health Technology Use with Implications for Coverage and Payment**

Key Questions	Direct or Indirect Coverage and Payment Pathways
<b>Where is the digital health technology being used?</b>	<ul style="list-style-type: none"> <li>• Home</li> <li>• Physician Office</li> <li>• Hospital</li> <li>• Post-acute care setting</li> <li>• Population health management</li> </ul>
<b>Who is using the digital health technology?</b>	<ul style="list-style-type: none"> <li>• Patients</li> <li>• Providers (i.e. physicians, nurses, care managers)</li> <li>• Health plans</li> <li>• Public health officials</li> </ul>
<b>How are regulatory requirements being addressed?</b>	<ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Making treatment decisions</li> <li>• Managing care at home</li> <li>• Remote monitoring to manage conditions</li> <li>• Population health management</li> <li>• Management of data on pandemics</li> <li>• Care management in pandemics</li> <li>• Cost</li> <li>• Quality</li> <li>• Health outcomes</li> </ul>

**SOURCE:** CapView Strategies Analysis; World Health Organization. (2018).

<https://apps.who.int/iris/bitstream/handle/10665/260480/WHO-RHR-18.06-eng.pdf;jsessionid=555E88F61E1E17CE8078F5B592C5B755?sequence=1>

Classification Of Digital Health Interventions V 1.0 A Shared Language to Describe the Uses Of Digital Technology For Health<sup>13</sup>

## 2 MEDICARE COVERAGE AND PAYMENT OF DIGITAL HEALTH TECHNOLOGIES UNDER EXISTING BENEFIT CATEGORIES—PATHWAYS, ISSUES, AND RECOMMENDATIONS

In the absence of an explicit benefit category, digital health technologies may be eligible for reimbursement by Medicare under existing pathways for direct coverage and payment or for indirect coverage as an allowable cost of service provision. While this report focuses on digital health technologies generally, it does not make recommendations for telehealth benefits, which do have specific statutory and regulatory coverage provisions (see Box 2.2 Coverage of Telehealth in Medicare). As presented in Chapter 1, the determination of which pathways are applicable depends on the setting(s) in which the technology is used, who the user is and the regulatory requirements for coverage. In each of the existing pathways, however, the full scope of coverage is limited by some of CMS's decisions about how to interpret statutory language, which effectively serves to impede permissible coverage under Medicare regulations in ways that may inhibit the adoption or diffusion of technologies.

At present, the only direct coverage pathways for digital health technologies occur in the benefits categories of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), which are applicable to certain digital health technologies used by patients in home and community settings to manage their own clinical care.

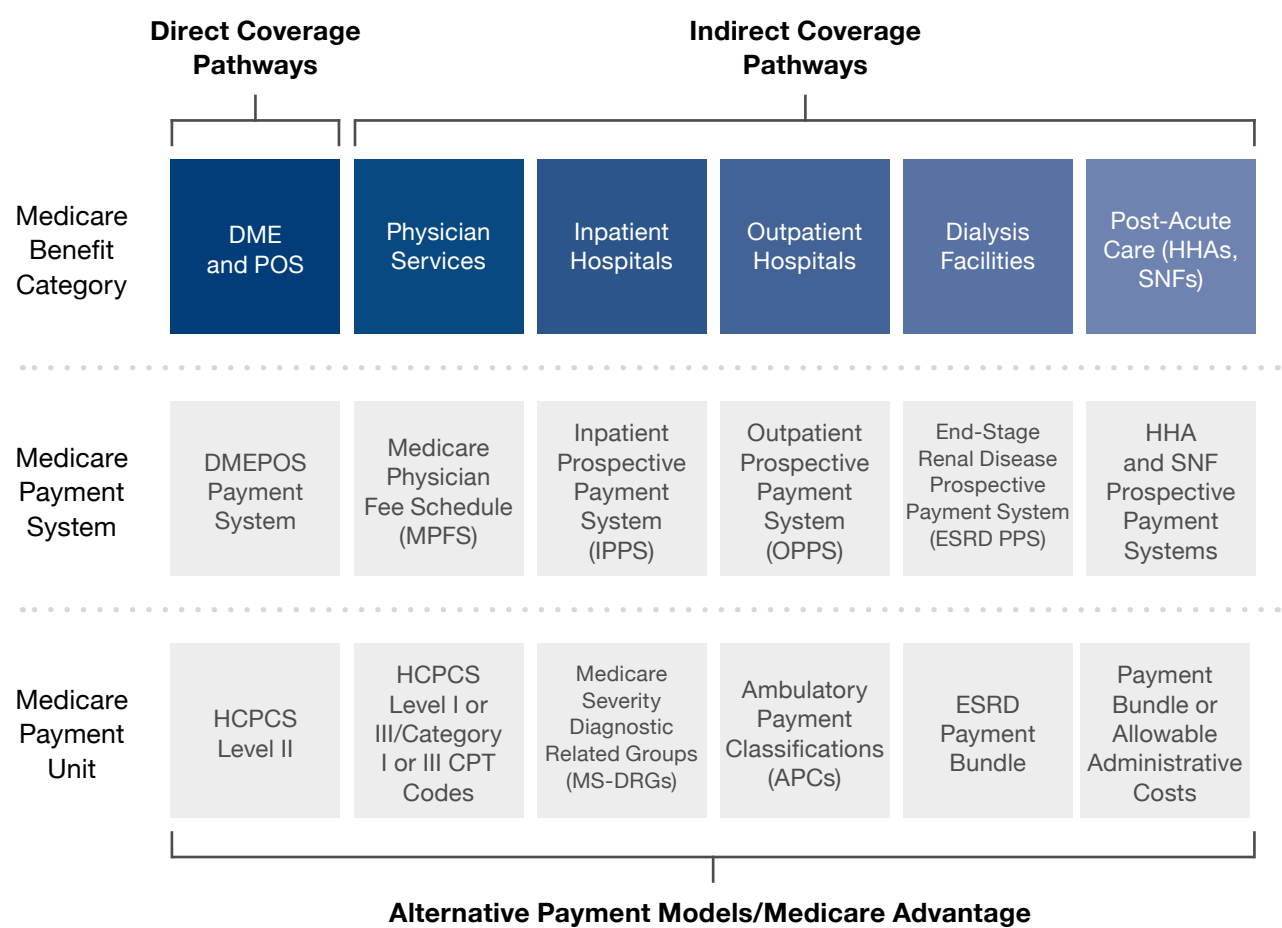
Digital health technologies may also be eligible for indirect coverage or incorporated into alternative payment models (APMs). Specifically, digital health technologies used by physicians and other health care providers may be eligible for indirect coverage under the payment systems listed below. Additionally, in APMs, digital health technologies may be used by providers to create greater efficiencies in patient care and to improve quality of care. APMs may provide “indirect coverage” opportunities for digital health technologies in a range of currently implemented and future models.

This chapter describes each of these coverage and payment pathways and identifies regulatory issues that may impact coverage.

- ▶ **Medicare Physician Fee Schedule.** Digital health technologies used by physicians and other providers in ambulatory care settings.
- ▶ **Medicare Inpatient and Outpatient Hospital Payments.** Digital health technologies used in hospital-based inpatient or outpatient settings.
- ▶ **End-Stage Renal Disease Payment System.** Digital health technologies used in dialysis facilities and home dialysis.
- ▶ **Post-Acute Care Provider Payment Systems.** Digital health technologies used to manage care furnished in post-acute care settings such as home health agencies (HHAs) or skilled nursing facilities (SNFs).
- ▶ **Alternative Payment Models.** Digital health technologies used in a variety of settings under new payment and delivery models being tested or already incorporated into the Medicare program.

For each pathway, recommendations have been developed to help clarify and expand coverage for new digital health technologies. Additionally, coverage and payment for certain digital health technologies may require the modernization of both direct and indirect payment policies. For example, implantable devices with software components may have broad use across various settings and may be used by both patients and providers. Components of these may be covered in the Medicare program across multiple benefit categories such as DMEPOS, under the Medicare Physician Fee Schedule (MPFS), and in hospital settings.

Figure 2.1 Coverage and Payment Pathways for Digital Health Technologies in Medicare



SOURCE: CapView Strategies Analysis

Direct Coverage Pathways for Digital Health Technologies Qualifying as Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

Some digital health technologies include equipment or devices used by patients in their homes and may qualify for payment under Medicare Part B by meeting the regulatory requirements for statutorily defined covered benefits categorized as DME, prosthetics or orthotic devices, or supplies to support use of the equipment or device.<sup>14</sup> Below, an overview of the current regulatory requirements is provided and key issues for coverage of digital health technologies under these direct coverage pathways are identified.

## Improving Digital Health Technology Coverage under the DME Benefit

DME are items that are medically necessary, prescribed by a physician and used in a patient's home. Digital health technologies offer an opportunity to improve care for a variety of conditions in the home and for use by patients. However, current regulatory requirements significantly limit coverage of innovative digital health technologies, specifically with regard to coverage and payment policies for software. Additionally, there are challenges with CMS's policies and processes for assigning new HCPCS codes necessary for billing and payment of new technologies.

### Narrow Regulatory Definition for DME Inhibits Coverage

The statutory provision for the DME benefit is broader than CMS's interpretation and implementation of the current regulatory requirements for coverage. The statute's definition provides a non-exhaustive list of qualifying covered items—such as wheelchairs and blood glucose monitors—and the only specific requirement under the statute is that the equipment be used in a patient's home.<sup>15</sup> The statute would allow for wider coverage of digital health technologies than is possible under the narrower definition used in regulations today.

However, CMS has established more prescriptive and limiting requirements for DME through regulations.<sup>16</sup> The regulatory requirements for DME under 42 CFR 414.202 are that DME:

- Can withstand repeated use;
- Has an expected life of at least three years (effective with respect to items classified as DME after January 1, 2012);
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of an illness or injury; and
- Is appropriate for use in the home.<sup>17</sup>

All requirements must be met for an item to be considered DME under the regulations. Additionally, Medicare pays for “supplies for DME,” (i.e. items that are necessary for the effective use of DME).<sup>18</sup>

The regulatory requirements for DME create barriers for coverage of many digital health technologies because the regulations do not allow flexibility for the coverage of software applications used for medical purposes—especially those that can be used on personal home computer devices. First, CMS requires that in multi-component devices, the medically necessary component must be the durable component.<sup>19</sup> In other instances, where software is an integral component of the covered DME, the software—and the advancements in care that the software offers—are not sufficiently covered by current payment policies. Finally, CMS's process for making decisions on coding and coverage may slow access to breakthrough technologies which could provide innovative and new therapies for patients.

### Box 2.1 Evolving DME Coverage: CMS's Coverage of the Therapeutic Continuous Glucose Monitor (CGM)

In January 2017, CMS issued a CMS Ruling (CMS-1682-R) on the classification of therapeutic continuous glucose monitoring (CGM) systems as DME. CMS had not previously recognized CGM as DME. The ruling makes a number of determinations to conclude that therapeutic CGM devices meet the requirements for coverage as DME, including:

1. **FDA approval of “therapeutic” CGMs for treatment decisions met requirement that the device was necessary for treatment or diagnosis.** To qualify for coverage as DME, CGMs needed to meet the threshold for coverage of being necessary for treatment or diagnosis under Social Security Act Section 1862(a)(1)(A).
2. **Identified the “receiver” as the medically necessary component and determined it was durable.** CMS requires that for multi-component devices to qualify as DME, the medically necessary component must be durable. CGMs are composed of three components: a glucose sensor, a transmitter, and a receiver. CMS determined that the receiver was the medically necessary component of the CGM. Further, CMS determined that the receiver met the minimum life requirement of three or more years.
3. **Therapeutic CGM fulfills remaining DME requirements.** CMS also discussed how the therapeutic CGM met other requirements for DME.

CMS has also recently expanded permissible use of personal devices with CGMs, stating that “[a]fter a thorough review of the law and our regulations, CMS is announcing that Medicare’s published coverage policy for CGMs will be modified to support the use of CGMs in conjunction with a smartphone.”<sup>20</sup>

### Coding Process May Delay Access to Breakthrough Devices

DME must have a HCPCS Level II code for payment purposes. CMS establishes these codes through an internal workgroup that reviews applications for new codes and revisions to existing codes.<sup>21</sup> CMS has implemented a bi-annual review of applications for HCPCS codes and changes. At present, there is no fast-track option for DME cleared by FDA as a “breakthrough device.” Even with a HCPCS Level II code, unless and/or until there is a national coverage determination, coverage and payment will be determined on an individual (ad hoc) basis by Medicare claims processors. This process for coding and coverage may delay access to breakthrough technologies that offer more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Further, CMS's approach of assigning a HCPCS code without decisions on coverage and payment may slow diffusion of and access to digital health technologies. As part of CMS's regulatory reviews, the agency should examine the implications of its coding process on the diffusion of new, innovative digital health technologies.

Addressing Barriers under DME

Currently CMS's regulatory definition narrows the broad statutory definition of DME and limits coverage of digital health technologies, especially software-based technologies that can be used on devices in the home. The recommendations presented in Table 2.1 below would create a pathway for better coverage of software-driven technologies under DME, address software advances in otherwise covered DME, and would speed the process to coverage and payment for FDA breakthrough technologies. Specifically, the recommendation to create a pathway for coverage of software or applications that can be used in combination with home devices will advance coverage of these technologies for home use and better align with how patients are using new digital health technologies.

Table 2.1. DME Coverage Issues and Recommendations

Coverage Issue	Recommendations
Software as DME	
<p><b>Software, applications or algorithms on their own are not eligible to be covered as DME.</b></p> <p><b>Requirement that DME “primarily and customarily be used to serve a medical purpose” prohibits coverage of smart devices.</b> The requirement that the device must be used primarily to serve a medical purpose has created limited coverage of smart devices that could serve as a display function for medical applications covered as DME.</p> <p><b>Durability requirements.</b> CMS's definition of durability (minimum life requirement of three years) prohibits wider coverage of digital health technologies, including software and algorithms, and is too limited.</p>	<p><b>1-A. Create a regulatory pathway under DME for software (or an application)</b> that is “primarily and customarily” used to serve a medical purpose but can be used on any device that can satisfy the other durability requirements (e.g. laptops, home computers, smartphones, iPads, etc.) even if the device is not exclusively used for the software or application. The home computing device is not covered as DME or as a supply.</p> <p>When software serves the medical purpose, CMS should create the flexibility for its coverage with its use on home devices that meet durability requirements.</p> <p>(This recommendation divides the regulatory requirements for DME between the software and the home device used to display the software/application.)</p> <p><b>1-B. All other non-software components should be covered and coded independently as DME and/or supplies</b> and not bundled into the software supply allowance/payment rate. <b>If software is covered as DME, then major or clinically meaningful software updates should be covered as supplies</b> (routine updates are currently considered normal/routine servicing of digital health technologies).</p>



**Table 2.1. DME Coverage Issues and Recommendations (cont.)**

Coverage Issue	Recommendations
<b>Software Integral to Otherwise Covered DME to be Covered as Supply</b>	
<b>Software as supply for otherwise covered DME.</b> CMS's non-recognition in regulations or sub-regulatory guidance of software as a supply that is critical for the adequate functioning of equipment otherwise covered as DME or implanted devices limits coverage and access.	<b>1-C. Cover software as a supply</b> when it is clinically meaningful and integral for the appropriate functioning of otherwise covered DME or when it provides new functionality. This will also include coverage for clinically meaningful software <b>upgrades</b> for software associated with the DME as a supply. However, all the components enabled and used with the software should be covered, coded and paid independently from the software as a supply.
<b>Breakthrough Technologies</b>	
<b>FDA breakthrough designations.</b> Coverage of breakthrough technologies is limited/slowed by CMS's process for recognizing digital health technologies within DME.	<b>1-D. Allow automatic assignment and payment</b> of HCPCS Level II codes for digital health technologies that are cleared or approved through FDA's Breakthrough Devices Program, used by a beneficiary in the home or community for a specified medical purpose as prescribed by a physician, and meet the other requirements under DME.
<b>Digital Therapeutics</b>	
<b>Software applications prescribed by physicians for use as therapy by a patient in their home are not currently covered as DME.</b>	<b>1-E. Create a regulatory pathway under DME to cover FDA cleared software as a medical device (SaMD)</b> which is for therapeutic use and is prescribed by a physician for use in a patient's home as DME.

**SOURCE:** AdvaMed/CapView Strategies Analysis

## Broadening Coverage of Digital Health Technologies under the Prosthetics and Orthotics Benefits

Prosthetics and orthotics are other examples of potential direct coverage pathways for digital health technologies as statutorily covered benefits under Medicare Part B.<sup>22</sup> Unlike DME, the statutory language and the regulatory definitions of prosthetics and orthotics are aligned. There are increasing opportunities to improve prosthetic and orthotic devices and their use through advances in digital technologies; however, this may be inhibited by regulatory or coding constraints. Specifically, CMS does not recognize software as a supply when it is integral to otherwise covered prosthetics or orthotics.

For example, recent advances have led to the development of an artificial pancreas system, which entails a combination of items used to monitor blood glucose levels, determine whether insulin levels should be adjusted, and then administer the appropriate amount of insulin without human intervention. The artificial pancreas system, as defined by FDA, includes an insulin infusion pump, CGM and software (algorithm). The system uses information collected from the CGM and the software determines adjustments. While the artificial pancreas system may be considered a prosthetic device, CMS does not currently recognize the software as a supply to the covered devices—an example of a policy where the software that is integral to the device’s functioning is not covered.

Coverage Issues for Digital Health Technologies under Prosthetics and Orthotics

Coverage of advancements in prosthetics and orthotics is currently limited in two important ways. First, the coverage pathway does not recognize software enhancements, which are essential to the functioning of certain prosthetics and orthotics. Second, similar to DME, covered prosthetics and orthotics are paid based on HCPCS Level II codes and therefore face comparable coding, coverage and payment delay issues for breakthrough and new technologies. Table 2.2 below presents recommendations to address these issues.

Table 2.2. Prosthetics and Orthotics Coverage Issues and Recommendations

Coverage Issue	Recommendations
Software Critical to Covered Prosthetic or Orthotic to be Covered as Supply	
<b>Definition of software as supply in certain prosthetics or orthotics.</b> CMS's non-recognition in regulation or sub-regulatory guidance of software as a supply that is critical for the adequate or improved functioning of otherwise covered prosthetics or orthotics creates access issues.	<b>2-A. Cover software as a supply</b> when it is integral for the appropriate functioning or provides new functionality to otherwise covered prosthetics (including implantables) or orthotics. This will also include coverage for clinically meaningful software upgrades for software associated with the prosthetic or orthotic as a supply. However, the devices enabled and used by the software should be covered and coded independently from the software.  <b>2-B. Cover clinically meaningful software upgrades as adjustments to covered prosthetics or orthotics.</b> For prosthetics or orthotics where a new software upgrade or functionality is available, the upgrade should be covered as an adjustment if prescribed by a physician.

**Table 2.2. Prosthetics and Orthotics Coverage Issues and Recommendations (cont.)**

Coverage Issue	Recommendations
Breakthrough Technologies	
<b>FDA breakthrough designations.</b> Coverage of breakthrough technologies is limited or slowed by CMS's process for recognizing digital health technologies in prosthetics and orthotics.	<b>2-C. Allow automatic assignment and payment</b> of HCPCS Level II codes for prosthetics and orthotics incorporating digital health technologies that are cleared or approved through FDA's Breakthrough Devices Program.

**SOURCE:** AdvaMed/CapView Strategies Analysis

## Indirect Coverage Pathways for Digital Health Technologies

Other than in the benefits categories of DME, prosthetics, orthotics and related supplies, opportunities for digital health technologies are limited to indirect coverage, as reviewed in the sections below. These indirect coverage pathways include payment of digital health technologies used by physicians, hospitals, dialysis facilities, and post-acute care providers.

## Accelerating Diffusion of Digital Health Technologies in Medicare Physician Services

Digital health technologies used by physicians and other health professionals to treat patients can be incorporated into physician payment codes paid under the MPFS. Digital health technologies covered under this pathway may include patient care management activities, remote monitoring of patients with chronic conditions, digital therapies, digital diagnostics and AI-based diagnostic technologies. Despite the potential and variety of digital health technologies to improve patient care through the provision of physician services, the process for establishing or integrating these technologies into physician payment codes limits the uptake and diffusion of these technologies in Medicare.

Medicare physician services are paid based on HCPCS Level I codes—which generally correspond to Category I CPT codes—and payment rates are included 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. CMS relies heavily on the American Medical Association's (AMA's) CPT Editorial Panel to determine which codes to adopt or revise in order to reflect in the AMA's Relative Value Scale Update Committee (RUC) to determine the appropriate relative value of codes.<sup>23</sup>

There are two ways digital health technologies can be incorporated into CPT/HCPCS codes: 1) via a new code; or 2) via review and revaluation of a current code. In general, new codes for digital health technology services can be established by the CPT Editorial Panel as a new Category I CPT code, if there is sufficient data on the use and costs of the new service, or as a new Category III CPT code, if data are insufficient.

CMS annually determines the payment rate for services and procedures associated with a code based on input from the RUC which evaluates: (1) the clinician work required to provide the service, (2) practice expenses associated with the service, and (3) professional liability insurance (PLI) costs. Revaluation of existing CPT codes through the RUC process allows for the incorporation of changes to the clinician's work and practice expense components, which may impact code value.

## **Recent Advances in Coverage for Digital Health Technologies under the MPFS**

Over the last few years, with guidance from the AMA, CMS has begun to acknowledge transitions in physician care by adopting more codes that reflect broader use of digital health technologies. CMS recently approved a series of codes which allow physicians to bill for remote physiological monitoring of patients.

In 2020, CMS also added new “E-codes” which are non-face-to-face codes for the reimbursement of “online digital evaluation services.”<sup>24</sup> Further, the AMA CPT Panel has created an AI workgroup to help address the need for greater AI integration into workflow and workforce supplementation for physicians.

More recently, in response to the COVID-19 pandemic, CMS has relaxed restrictions and limitations on the use of telehealth, remote physiological monitoring, and e-visits in Medicare in order to allow physicians and patients greater protection and flexibility in providing and receiving care during the pandemic.

## **Coverage Issues for Digital Health Technologies Used in Physician Services**

The lack of a clear path to establishing and using codes that cover innovative (new and emerging) advancements represents one of the largest regulatory issues for the coverage of digital health technologies used by physicians in Medicare. This includes assignment of codes for new technologies, as well as capturing the value of the technology appropriately in established codes when the technology advances the standard of care. The recommendations below suggest paths for addressing key issues (Table 2.3). CMS should also clarify how therapeutic digital technologies will be covered under the MPFS as they become increasingly available. Furthermore, the agency should clarify how and when physicians may use codes for these technologies, including the new remote physiological monitoring codes, as use may be limited by physician uncertainty about overlap or interactions with other codes.

**Table 2.3. Coverage Issues and Recommendations for MPFS**

Coverage Issue	Recommendations
<b>Breakthrough Technologies</b>	
<p><b>FDA breakthrough designation.</b> There is limited coordination between CMS and FDA, especially on the designation of breakthrough technologies and the subsequent use of this designation in Medicare coverage policy.</p>	<p><b>3-A. Allow automatic use/assignment of and payment</b> for Category III CPT codes for digital health technologies that are cleared or approved through FDA's Breakthrough Devices Program and are used by physicians.</p>
<b>Coverage for New and Emerging Technologies</b>	
<p><b>Lack of a specific pathway for coverage of new and emerging FDA-approved technologies for physician use.</b> For new and emerging digital health technologies, it can be difficult to appropriately value and diffuse the technology without assigned codes or appropriate coverage in codes for current services.</p> <ul style="list-style-type: none"> <li>• <b>Valuing costs.</b> Appropriate methodology for valuing the costs associated with training and use of digital health technology is limited and may result in practice expenses not accurately reflecting all the digital health technology's costs.</li> <li>• <b>Valuing work.</b> Methodologies to value digital health technologies do not address the “work” the software does and the efficiencies it creates for physicians.</li> </ul>	<p><b>3-B.</b> For new and emerging FDA-approved digital health technologies that are used by physicians, <b>automatically assign a Category III CPT code and payment level for new technology or develop a modifier</b> to use with existing CPT codes when the digital technology is used with the service.</p> <p><b>3-C. Develop method to incorporate the value of software into CPT codes</b> to address practice expense and/or work intensity for relative value units (RVUs). The value of services delivered by a physician to interpret or act on new digital health technology information should be included in work RVUs. The value of the software used to address improvements and efficiency in patient care should be factored into practice expense RVUs.</p> <p><b>3-D. Develop a subscription-based payment approach for physician-prescribed digital technologies and continued clinical monitoring.</b> This methodology should pay for continued use during the physician-recommended period of time and allow for maintenance, monitoring and adjustments by the physician.</p>

**Table 2.3. Coverage Issues and Recommendations for MPFS (cont.)**

Coverage Issue	Recommendations
<b>Digital Therapeutics</b>	
<b>No current coverage pathway or payment models exist for some digital therapies in MPFS.</b>	<b>3-E. Develop approaches for covering digital therapeutics, as a prescribed physician service.</b> A collaborative effort should include CMS working with the AMA, device manufacturers, and payers. This could include—but not be limited to—the subscription-based approach described in recommendation 3-D.
<b>Remote Physiologic Monitoring</b>	
<b>Use of remote physiological monitoring codes is currently limited.</b> The definition of “physiologic” in the introductory CPT language and the descriptors for remote physiological monitoring codes needs additional clarification. The term’s use and the type of items to which it applies are not fully defined and result in provider hesitation to utilize codes, fearing potential audits by CMS contractors investigating billing practices.	<p><b>3-F. Provide guidance on the use of remote physiological monitoring codes for physicians,</b> including examples of the types of digital health technologies that could be covered under remote physiological monitoring codes. Consider clarifying use of codes for acute conditions and other opportunities to expand and incentivize use.</p> <p><b>3-G. Create a modifier</b> for specified digital health technologies used with existing care management codes such as CCM, transitional care management (TCM) and other care management codes, that improve the efficiency of care or augment the care plan—especially for monitoring of non-physiological metrics for care management.</p> <p>Additionally, as “E-Codes” are new codes in the MPFS, CMS should monitor their use and consider stakeholder feedback on improving use of these codes.</p> <p><b>3-H. Develop a new process, outside of the traditional CPT process, to recognize and pay for services that can be delivered through telehealth or remotely,</b> like device interrogation and programming that are currently described by in-person CPT codes. This could also include payment for software upgrades and adjustments.</p>

**SOURCE:** AdvaMed/CapView Strategies Analysis



## Box 2.2 Coverage of Telehealth in Medicare

Telehealth services were first included in the 2001 Medicare Physician Fee Schedule after Congressional authorization in the Balanced Budget Act of 1997. Despite nearly 20 years of Medicare coverage and payment, use by beneficiaries and providers has been low. Only 90,000 beneficiaries used telehealth services on a fee-for-service basis in 2016—just 0.25 percent of the 35 million beneficiaries who obtained care through the original program, according to a 2018 report to Congress by CMS.

Limited use is attributed to narrow statutory and regulatory parameters defining Medicare reimbursement for telehealth services, including those restricting the geographic location, originating site, type of provider, and the type of technology used. While CMS has added new telehealth services to the list of those that are reimbursable through the annual MPFS rule, payment is generally made only for services meeting the requirements described below.

- **Originating sites.** Statutory requirement that beneficiaries must be present in physician offices, hospitals, critical access hospitals, rural health clinics, federally qualified health centers, hospital-based dialysis facilities, skilled nursing facilities, and community mental health centers.
- **Geographic location.** Statutory requirement limiting coverage and payment for services provided to beneficiaries in originating sites only if located in rural health professional shortage areas (HPSAs) or counties outside of Metropolitan Statistical Areas (MSAs).
- **Type of provider.** Statutory limits on the types of providers that can bill Medicare for telehealth services including physicians, nurse practitioners, physician assistants, nurse midwives, clinical nurse specialists, certified registered nurse anesthetists, clinical psychologists and clinical social workers, and registered dietitians or nutrition professionals.
- **Type of telecommunications system.** Regulatory requirement limiting coverage and payment to real-time audio and video only (i.e. not store-and-forward technologies).

Recognizing that the statute limited access to beneficial telehealth services, in 2018 Congress made a number of changes to increase the circumstances under which telehealth services could be reimbursed. The Bipartisan Budget Act of 2018 expanded telehealth coverage and payment for services to beneficiaries with end-stage renal disease and/or stroke by modifying specific geographic restrictions and the list of originating sites for each condition. That legislation also authorized new telehealth flexibilities for Medicare Advantage plans and Medicare Accountable Care Organizations so that beneficiaries could access telehealth services from more locations, including their homes. Furthermore, the 2018 SUPPORT for Patient and Communities Act, enacted in response to the opioid crisis, increased telehealth access for beneficiaries with substance use disorders by expanding the list of originating sites and by modifying geographic restrictions.

In response to COVID-19, CMS has waived nearly all Medicare regulatory and statutory telehealth requirements for the duration of the public health emergency—acknowledging the technology’s potential to increase access to care for all beneficiaries regardless of geographic location or originating site. An early study following the emergency waivers found that nearly 30 percent of all outpatient visits were being provided via telehealth. Changes to the Medicare statute will be needed to maintain much of this access and will be dependent on the assessment of budgetary impacts and other implications of this expanded coverage. However, achieving these statutory changes can be a slow-moving process and delay access to high-value services for beneficiaries – underscoring how critical it is for CMS to use existing coverage and payment pathways wherever possible to improve beneficiary health and outcomes.

**SOURCE:** Quinn, W. V. (2019, August). *AARP Fact Sheet—Telehealth and Medicare: What Is Covered*. AARP Public Policy Institute. <https://www.aarp.org/content/dam/aarp/ppi/2019/08/telehealth-medicare-what-is-covered.doi.10.26419-2Fppi.00080.001.pdf>; and Mehrotra, A. et al. (2020, May 19). *The Impact of the COVID-19 Pandemic on Outpatient Visits: A Rebound Emerges*. The Commonwealth Fund. <https://www.commonwealthfund.org/publications/2020/apr/impact-covid-19-outpatient-visits>

## Coverage of Digital Health Technologies in Inpatient Hospitals

Digital health technologies used in hospitals that Medicare will pay for under the inpatient prospective payment system (IPPS) are part of “bundled” costs included in Medicare Severity-Diagnostic Related Groups (MS-DRGs). Updates to DRGs may include the costs of digital health technologies if the digital health technology is a key component of patient care services; however, there is a two- to three-year time lag for updating allowable costs within DRGs.

The inpatient new technology add-on payment (NTAP) program is a payment system created by Congress and implemented by CMS through the rule-making process to encourage the uptake of new and potentially costly medical technologies.<sup>25,26</sup> NTAP payments are not subject to budget neutrality requirements so provide new funding for approved technologies. The new technology must meet the following criteria to qualify for an NTAP payment:

- **Substantial Clinical Improvement.** The technology represents an advance that “substantially improves” the diagnosis or treatment of Medicare beneficiaries compared to technologies previously available;
- **Newness.** The technology does not have sufficient data for CMS to reflect the technology in the DRGs, usually a period of 2-3 years (until the costs can be incorporated into the DRGs); and
- **Cost Threshold.** Payment under the current MS-DRG is inadequate to cover the costs of the new technology based on a cost threshold established by CMS.

## CMS Eases Coverage of Breakthrough Technologies in Inpatient Settings under NTAP

For 2020, CMS finalized a proposal where devices that are part of FDA's Breakthrough Devices Program and receive FDA marketing clearance will only need to show they meet the cost criteria for NTAP. The breakthrough designation will automatically meet CMS's requirements for newness and the agency will waive the need to demonstrate substantial clinical improvement because CMS has a similar criterion for Breakthrough approval.<sup>27</sup>

## Coverage Issues for Digital Health Technologies Used in Inpatient Hospitals

Although CMS has recently improved coverage for new technologies under NTAP, CMS should consider other regulatory flexibilities that may be needed to encourage uptake and use of digital health technologies. Use of these technologies may be limited by implementation costs that may not meet the cost threshold under NTAP but may still be too high. NTAP methodology also does not accurately value the potential of the digital health technology. In fact, many technologies may contribute to hospital cost savings, yet the cost of the digital health technology does not meet the NTAP cost threshold levels, despite its contribution to overall decreases and improvements in quality.

Another barrier to wider adoption of digital health technologies under the IPPS is the time lag associated with incorporating the costs into the MS-DRGs. Our recommendations for addressing these barriers are presented in Table 2.4 below.

**Table 2.4. Coverage Issues and Recommendations for Inpatient Hospitals**

Coverage Issue	Recommendations
<b>Breakthrough Technologies</b>	
<b>New Technology Add-on Payment (NTAP) pathway limited.</b> NTAP thresholds may be too high for digital health technologies. NTAP methodology does not accurately value the potential of digital health technologies. Although many technologies contribute to hospital cost savings and provide important care management tools, the cost of the digital health technology does not meet the cost threshold levels.	<b>4-A. Review NTAP requirements</b> with regard to digital health technologies or medical devices with software that provides new functionality, such as providing process improvements in care delivery to determine if changes should be made to encourage uptake, including the establishment of a lower cost threshold to receive payment.
<b>Incorporation into MS-DRGs.</b> Misassignment to DRGs and the two-to-three-year lag time for new cost-data inputs for DRGs limit the diffusion of digital health technologies.	<b>4-B. Implement a process to improve the assignment of MS-DRGs</b> when a new digital health technology is incorporated to more appropriately reflect costs and accuracy of payment and uptake.

**SOURCE:** AdvaMed/CapView Strategies Analysis

## Coverage of Digital Health Technologies in Outpatient Hospitals

Use of digital health technologies in hospital outpatient settings is part of an increasing shift in care away from inpatient hospital treatments. It is also likely, especially post-pandemic, that more care will be delivered in outpatient, community or home settings and increased use of digital health technologies will help facilitate these changes.

Under the outpatient prospective payment system (OPPS), Medicare pays for outpatient hospital services based on ambulatory payment classifications (APCs). Technologies are assigned to APC cost groupings based on resource and clinical criteria. There are also payments made for outlier adjustments for very high-cost services and pass-through payments for some new technologies.

Pass-through payments are another way that the OPPS accounts for new technologies and are used for specific drugs, biologics, and devices that providers use in the delivery of services.<sup>28</sup> The intent of pass-through payments is to encourage access to new technologies. Pass-through payments and the NTAP have similar review criteria—newness, high cost, and substantial clinical improvement. However, pass-through payments are required to be budget neutral, unlike NTAP which provides new funding without regard to budget neutrality, and can only account for two-percent of estimated total OPPS payments.<sup>29</sup>

## CMS Eases Pass-Through Payment Eligibility for Breakthrough Technologies

For 2020, CMS finalized a proposal where devices that obtain FDA clearance or approval under the Breakthrough Devices Program only need to show they meet the cost criteria. Technologies with the breakthrough designation will meet CMS's requirement for newness and the agency will waive the substantial clinical improvement criteria.<sup>30</sup>

## Coverage Issues for Digital Health Technologies Used in Hospital Outpatient Settings

Under OPPS, the misassignment of new technologies to lower-cost APCs is an issue as this does not accurately reflect the costs of the new technologies. Additionally, the two-to-three-year lag time in obtaining cost data from new technologies delays appropriate reimbursement for use and may inhibit diffusion. Finally, CMS should consider opportunities to improve the transitional pass-through payment requirements for digital health technologies.

**Table 2.5. Coverage Issues and Recommendations for Outpatient Hospital Setting**

Coverage Issue	Recommendations
<b>Improve transitional pass-through payments.</b> The transitional pass-through cost threshold may preclude some digital health technologies from diffusing to outpatient settings. Payments also need to better account for the potential value of the digital health technology. Many technologies contribute to hospital cost savings, but the cost of the digital health technology does not meet the cost threshold levels and therefore diffusion and uptake is limited.	<b>5-A. Modify transitional pass-through payment requirements</b> for digital health technologies to lower-cost thresholds.
<b>Incorporation into APCs.</b> Misassignment of new technologies to lower-cost APCs is an issue for appropriate incorporation into the OPPS. Additionally, the two-to-three-year lag time in obtaining cost data from a new technology limits the diffusion of the digital health technology and its appropriate incorporation into an APC.	<p><b>5-B. Implement a process to review APC assignments</b> and ensure new digital health technologies are appropriately valued and included in the APC determination.</p> <p><b>5-C. Implement a process to annually review HCPCS code value changes</b> to determine any necessary corresponding changes to APC assignments.</p>

**SOURCE:** AdvaMed/CapView Strategies Analysis

## Coverage of Digital Health Technologies for ESRD

In 1972, Congress extended Medicare coverage to patients with end-stage renal disease (ESRD) regardless of age.<sup>31</sup> Among this benefit category's benefits are dialysis treatments—both at facilities and in the home—as well as dialysis patient care management by physicians. CMS pays dialysis facilities a bundled payment amount per dialysis treatment for both facility and in-home dialysis under the ESRD prospective payment system (ESRD PPS). The bundled payment to facilities covers treatment services and ESRD-related drugs, laboratory services, and medical equipment and supplies.<sup>32</sup> Physicians and practitioners that manage care for ESRD patients can bill for an ESRD Monthly Capitation Payment (MCP).

## Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies

Beginning January 1, 2020, CMS implemented a new transitional add-on payment adjustment for the use of new and innovative renal dialysis equipment or supplies by ESRD facilities. This adjustment, called the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES), is for equipment and supplies that “represent an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.”<sup>33</sup> CMS will pay the TPNIES for two years, then the equipment or supply will qualify as an outlier service and no change to the ESRD PPS base rate will be made.<sup>34</sup>

## Coverage Issues for Digital Health Technologies used for ESRD Patients

The bundled payments made to facilities and to physicians under the MCP do not incentivize the use of certain digital health technologies in services and exclude certain key services that incorporate digital health technologies, such as remote patient monitoring or electronic communications between patients and providers. CMS should consider opportunities to incorporate these into the ESRD payment structure.

**Table 2.6. Coverage Issues and Recommendations for ESRD PPS**

Coverage Issue	Recommendations
<p><b>Does not incentivize the use of services which may be provided via digital health technologies under bundled payments.</b> Neither the ESRD bundled payment nor the MCP include coverage for services provided that may incorporate digital health technologies.</p> <p><b>Face-to-face requirements for ESRD coverage.</b> To receive the MCP, a physician (or practitioner) must furnish at least one face-to-face visit per month to the beneficiary.</p>	<p><b>6-A. Include services associated with new technologies in the TPNIES</b> and clarify this inclusion in regulation.</p> <p><b>6-B. Clarify that physicians can bill RPM codes</b> used for monitoring of ESRD patients in addition to MCP.</p> <p><b>6-C. Make permanent changes to relax the requirement for face-to-face or in-person visits</b> for MCP payment, allowing phone and asynchronous visual visits to qualify.</p>

**SOURCE:** AdvaMed/CapView Strategies Analysis

## Coverage of Digital Health Technologies in Home Health Agencies (HHAs)

Opportunities exist for digital health technologies to be covered under the home health benefit for Medicare beneficiaries that are restricted to their homes and need skilled care (from a nurse or physical, occupational or speech therapist) on a part-time or intermittent basis.<sup>35</sup> This benefit is distinct from DME where items can be used in a home for a medical purpose but do not require the patient to be homebound.

In 2019, CMS began recognizing the costs for RPM under the Medicare home health benefit and changes were made to the regulations to include the costs of RPM as allowable administrative costs.<sup>36</sup>

## Coverage Issues for Digital Health Technologies used by HHAs

CMS should give HHAs more flexibilities to use digital health technologies that support home health care by evaluating opportunities to cover the costs of implementing and using these technologies under administrative costs, as presented in Table 2.7



**Table 2.7. Coverage Issues and Recommendations for HHAs**

Coverage Issue	Recommendations
<b>Better explanation of definition of allowable administrative costs for new technologies for HHAs is needed.</b> While allowable RPM costs are new for HHAs, there are additional opportunities for HHAs to use digital health technologies in the provision and management of care for beneficiaries that are not currently part of the home health payment structure.	<b>7-A. Review HHA payment system</b> to evaluate opportunities to include digital health technologies other than RPMs as allowable administrative costs.

**SOURCE:** AdvaMed/CapView Strategies Analysis

## Coverage of Digital Health Technologies in Skilled Nursing Facilities (SNFs)

There are increasing opportunities for SNFs to use digital health technologies in the delivery of care. SNFs may implement digital health technologies and monitoring devices to improve patient care, monitor patient vitals, and monitor for patient activity and falls. Medicare pays SNFs using the SNF prospective payment system (SNF PPS). SNFs are paid a predetermined daily rate which covers all operating and capital costs that “efficient facilities would be expected to incur in furnishing most SNF services.”<sup>37</sup> Some high-cost and low-probability ancillary services are paid for separately.

## Coverage Issues for Digital Health Technologies used by SNFs

Adoption and diffusion of digital health technologies may be limited in SNFs because of implementation costs and lack of flexibility on covered use. CMS should consider ways to encourage greater use and diffusion of digital health technologies that improve patient care in SNFs. Our recommendation is presented in Table 2.8 below.

**Table 2.8. Coverage Issues and Recommendations for SNFs**

Coverage Issue	Recommendations
<b>SNF payment methodology does not include opportunities to incorporate digital health technologies.</b> The SNF payment methodology does not adequately value or incorporate digital health technologies into the payment system.	<b>8-A. Review SNF payment system</b> to evaluate opportunities to encourage use of digital technologies to improve care/reduce costs and allow digital health technologies to be included as allowable administrative costs—as in the case of home health services.

**SOURCE:** AdvaMed/CapView Strategies Analysis

Coverage of Digital Health Technologies in Alternative Payment Models (APMs)

The Center for Medicare and Medicaid Innovation (CMMI) tests new payment and health care delivery models that relax certain requirements to evaluate if these changes lead to lower costs and better care. APMs have been developed to target specific clinical conditions, care episodes, or populations, as well as implement broader, value-based programs. By incorporating quality incentives into fee-for-service payment formulas, provider payments under an APM are partially dependent on the delivery of high-quality and cost-efficient care. Over the last decade, CMMI has established more-than 35 such models and programs, including accountable care organizations and bundled payment models.<sup>38</sup>

Coverage Issues for Digital Health Technologies in APMs

Because APMs give participating providers greater flexibility and incentives to improve patient care and outcomes, and to reduce costs, they may offer a pathway for digital health technology diffusion. However, models often do not provide clear incentives for digital health use, such as linkages to quality measures that are used to evaluate performance and payment or temporary carve-outs of digital health technology investment costs during a testing period. Recommendations to support the adoption and use of digital health technologies in ways consistent with CMMI’s mission are presented in Table 2.9.

Table 2.9. Coverage Issues and Recommendations for Digital Health Technologies in APMs

Coverage Issue	Recommendations
<b>Lack of incentives for inclusion of digital health technologies into APMs.</b> Current APM participants may not be aware of the potential technologies available for incorporation into payment models. There are disincentives for providers to invest in digital health technologies—including the fact that APM benchmarks often do not reflect the costs of new technologies.	<b>9-A. Incentivize use and testing of digital health technologies in APMs</b> (e.g. through quality measures, bonus payments, or technical assistance to support implementation of technologies) and require CMS/CMMI to assess their impact on quality, patient outcomes, and health care costs.
<b>Methods to show value of digital health technologies for APMs are lacking.</b> Demonstration of the “value proposition” of the use of digital health technologies may be difficult because of lack of data and quality measures.	<b>9-B. Develop a demonstration to evaluate opportunities for digital health technologies to improve quality and health outcomes and decrease Medicare costs.</b> For example, CMMI could test a temporary carve-out of the costs of new digital health technologies from the calculation of benchmarks and actual spending totals.

SOURCE: AdvaMed/CapView Strategies Analysis

## 3 DIGITAL HEALTH TECHNOLOGIES AND MEDICARE ADVANTAGE (MA)

Digital health technologies may be covered through both “direct” and “indirect” coverage pathways by Medicare Advantage (MA) plans. MA plans are private plans that participate in Medicare, offering an alternative to traditional fee-for-service (FFS) coverage. In general, MA plans must cover all of the items and services available under Medicare Parts A and B to individuals enrolled in the plan and can cover and pay for digital health technologies in similar ways to traditional Medicare. However, MA plans may also provide additional benefits known as supplemental benefits, under which they have flexibility to cover other digital health technologies that Medicare FFS may not cover. As a result, MA plans have flexibility under supplemental benefits to cover digital health technologies beyond those covered under traditional Medicare.

For coverage of traditional Medicare benefits, MA plans are bound by Medicare's national and local coverage and benefit determinations, including decisions of coverage, non-coverage, and limited coverage. Additionally, Medicare national and local coverage decisions may impede inclusion of digital health technologies in MA. In the absence of a positive coverage decision by Medicare for a digital health technology, MA plans may be unlikely to extend coverage to these technologies without greater encouragement by CMS or demonstrations of value to the health plan—even though the MA plan may be technically permitted to do so as part of the supplemental benefits they offer.

Congress and CMS have recently expanded flexibilities associated with MA supplemental benefits, which may permit greater coverage of digital health technologies by plans. First, beginning in 2019, CMS expanded its interpretation of the requirement that the supplemental benefits be “primarily health related”. CMS also specifically permitted the use of supplemental benefits for coverage of items related to daily maintenance of health (e.g. smoke detectors) and long-term services and supports. Therefore, MA plans may now cover a much wider array of benefits that could include digital health technologies that support the care and health of beneficiaries.

Second, the Congress expanded MA plan supplemental benefits under the Bipartisan Budget Act of 2018 by allowing MA plans to offer a new category of supplemental benefits for “chronically ill enrollees”.<sup>39</sup> This new statutory authority is broad in terms of the clinical conditions plans may address in their benefits for chronically ill beneficiaries and the types of supplemental benefits plans may offer, including benefits that address social determinants of health.

More recently, in response to the COVID-19 pandemic, CMS has announced additional flexibilities related to telehealth and digital health technologies to help reduce the risk of spreading the virus and to make care more accessible during the pandemic. Specifically, CMS announced that MA plans may use diagnoses from telehealth services for risk adjustment, which is used in the determination of MA payments.<sup>40</sup> CMS has also permitted MA plans to change benefits mid-year so long as the benefits are related to COVID-19. In particular, CMS will permit plans to purchase smartphones and tablets for enrollees as supplemental benefits as long as the devices are used primarily for health-related purposes and are locked except for certain uses such as communications with providers and remote monitoring.<sup>41</sup>

CMS also recently finalized a rule that relaxed network adequacy requirements for MA plans when they contract with telehealth providers in certain specialties including dermatology, psychiatry, cardiology, and primary care among others.<sup>42</sup>

### Other Opportunities under Medicare Advantage Plans

MA plans may also see value in using digital health technologies beyond direct patient care - similar to how commercial plans are beginning to explore their use (see Box 3.1). Specifically, MA plans are exploring opportunities to use digital health technologies that help manage care for their enrollees, including use of technologies by the health plan itself, as opposed to a patient or provider. MA plans may integrate digital health technologies into care management protocols that help lower total cost of care, reduce use of services that are not medically necessary or appropriate, or manage emergency department visits. MA plans also have a strong incentive to perform well on quality measures, particularly those that are used for the CMS's MA Star Ratings program, which may encourage use of technologies to advance quality of care. Under the MA Star Ratings program, plans receive quality bonuses and incentives for higher performance.

Coverage Issues for Digital Health Technologies in Medicare Advantage

While Medicare Advantage plans have flexibility to offer extra benefits that rely on or incorporate the use of digital health technologies, there are barriers to adoption and diffusion in MA. Plan incentives to adopt digital health technologies may be limited by MA payment policies, data on care management outcomes, and quality measures. Additionally, some potentially advantageous digital health technologies may not meet the criteria for inclusion as an extra supplemental benefit. Table 3.1 presents recommendations for strengthening coverage of digital health technologies by MA plans.

Table 3.1. Medicare Advantage Coverage Issues and Recommendations

Coverage Issue	Recommendations
<b>Lack of standardized methods or data to demonstrate value.</b> Difficulty demonstrating the value of digital health technologies to MA plans may impede plan interest in indirect coverage.	<b>10-A. Implement quality or other plan measures that assess use of digital health technologies</b> that improve patient care, efficiency.  <b>10-B. Create CMS workgroup</b> to help inform CMS on plans’ data requirements, opportunities for possible guidance on data requirements for coverage of digital health technologies, and to create a greater exchange of information on digital health technologies between plans and CMS. This could improve plan assessments of value and data for determining coverage.
<b>Medicare national and local non-coverage decisions may impede inclusion of technologies in MA.</b> MA plans are unlikely to cover digital health technologies beyond national and local coverage decisions—even under supplemental benefits—without greater encouragement by CMS or demonstration of digital health technologies’ value.	<b>10-C. Incentivize MA plans to provide and deploy new digital technologies</b> by issuing guidance addressing potential of supplemental benefits to improve quality and decrease cost.

SOURCE: AdvaMed/CapView Strategies Analysis

### Box 3.1 Commercial Plan Perspectives on Coverage of Digital Health Technologies

While commercial plans have the flexibility to make their own determinations for coverage and payment of digital health technologies, many are still grappling with how to evaluate the value of these new technologies. Medicare continues to serve as a primary framework for payer decision-making processes regarding the coverage and payment of digital health technologies used by patients and providers. Commercial payers are testing and integrating digital health technology advancements into their care management platforms and exploring wider availability and use for members. Recently, other groups such as pharmacy benefit managers like Express Scripts have started to offer digital health technology “formularies” to assist plans in coverage determinations of new digital health technologies.

Digital health technologies that address “cost drivers” are more likely to be covered or adopted by commercial plans. Plan priorities include managing care more effectively for chronic conditions, such as chronic obstructive pulmonary disease (COPD), and developing programs to manage inpatient and long-term care utilization. Commercial plans are also exploring the use of digital health technologies that use AI and predictive analytics to identify patients in need of “high-touch” or intensive interventions. As commercial plans assess ways to better utilize or cover digital health technologies, there may be opportunities for collaboration across public and private payers to evaluate digital health technologies’ adoption for clinical care management and coordination as well as their diffusion.

**SOURCE:** *AdvaMed/CapView Strategies Analysis*



# 4 A ROADMAP FOR HARNESSING THE POTENTIAL OF DIGITAL HEALTH TECHNOLOGIES IN MEDICARE

Innovation in digital health is occurring at a brisk pace as the ability to collect, analyze, and use data to manage patient care grows. As the single largest payer of health care in the U.S., Medicare can lead efforts to deploy digital health solutions to meet the challenges of improving care and reducing costs. This chapter makes recommendations on the leadership role CMS can take not only to address coverage and payment issues within the Medicare program, but also to foster broader collaboration across policy makers and stakeholders. Using this approach, the potential of digital health technologies can be fully harnessed in the marketplace.

## Strategies for Addressing Cross-cutting Coverage Issues in Medicare and in the Commercial Marketplace

As outlined in Chapters 2 and 3, CMS can move forward with basic regulatory updates to address coverage issues impeding access to digital health technologies in Medicare. Current coverage and payment pathways, designed for traditional technologies and devices, can be modernized to address the unique issues associated with digital health technologies. The analysis presented in this report demonstrates clear pathways and mechanisms—within the constraints of current law—for regulatory modernization that could significantly improve access to new standards of care through the use of digital health technologies.

- **CMS should review all Medicare regulations, policy guidance, and program manual instructions to determine which changes should be made to accommodate digital health technologies.** With the growth in digital health technologies—and using this report as a guide—CMS should assess whether its regulations are in step with the evolution of health care delivery and changes in the standards of care. This review should also include CMS's approach on the HCPCS coding process to assess its impact on the diffusion of digital health technologies.

Further, there are opportunities for CMS to learn from its response to the COVID-19 pandemic, during which it granted Medicare waivers to increase flexibility in the program. These waivers facilitated needed access to health care services and allowed continued care management throughout the public health emergency. CMS's waivers allowed for rapid expansions of digital health technologies such as telehealth and remote physiological monitoring which were critical to maintaining care during the pandemic. The speed with which digital communications platforms were used underscores how these technologies can build a more nimble, resilient health care system – and the importance of further evaluating digital health technologies in creating a patient-focused, community-based health care system (see Box 4.1).

- **CMS should assess the impact on care delivery and access from expanded coverage of digital health technologies under the COVID-19 public health emergency waivers and make these policies permanent.** As an important step, CMS should finalize recent proposals to make telehealth use permanent for HHAs. CMS should also evaluate the potential of extending the waivers to further expand telehealth services and the use of remote physiologic monitoring, electronic information exchange, and E-visits.
- **Using the COVID-19 public health emergency waivers as a model, CMS should explore the expansion of coverage policies for new and currently non-covered digital health technologies.** CMS should evaluate the potential of new and emerging digital health technologies to expand access to care, to improve quality and health outcomes, to promote patient safety, and to decrease Medicare program costs. Using these as measures of potential impact, flexibilities for coverage of the following types of technologies should be explored:
  - Broader coverage for smart devices,
  - Expanded use of communication devices,
  - Coverage of Software as a Medical Device (SaMD), if approved by FDA, to facilitate communication, and
  - Broader access to digital diagnostic testing.

Finally, Medicare has a unique position in the health care sector not only as the largest payer, but also as a standard setter in the marketplace on data, quality measurement, and health outcomes analysis. By establishing new collaborations to address major challenges across federal agencies, payers, providers, and patients, CMS can facilitate exchange of lessons learned and best practices to help accommodate and promote innovation in health care through the diffusion of innovative digital health technologies.

- **HHS should create an Inter-agency Task Force on Digital Health Technologies.** The purpose of an inter-agency task force would be to explore policies to improve access and coverage for digital health technologies, including coordination across federal and state agencies. Its mandate would include:
  - Coordinating the policy agendas and regulatory activities of CMS, FDA, and the Office of the National Coordinator for Health Information Technology (ONC),
  - Assessing data on digital health technologies,
  - Identifying pathways to coverage under existing Medicare benefit categories,
  - Developing uniform nomenclature to be used by FDA, CMS, ONC, other federal agencies, payers and health systems, and
  - Informing HHS policies on digital health technologies, in particular the joint CMS-FDA parallel review process and workgroups on digital health technologies.

- **HHS should convene a Public-Private Consortium to support the use and diffusion of digital health technologies.** Led by CMS and FDA, the Public-Private Consortium would include payers, manufacturers/developers, providers, patients, and trade associations. Its goals would be to develop common methodologies, metrics, and approaches to assessing data on the impact of digital health technologies on quality, health outcomes, and total cost of care. This could include the establishment of a framework for digital companies to use for generating evidence for payers.

Because digital health technologies are advancing quickly and standards of care are changing rapidly, it is important that CMS move to expedite regulatory modernization efforts. Table 4.1 presents broad, cross-cutting recommendations for strengthening coverage of digital health technologies in Medicare and fostering collaboration across the health care landscape. However, if CMS cannot act in a timely manner, legislative action may be required. Specifically, Congress should first require CMS to modernize its approach to coverage and payment for digital health technologies, and also consider the creation of new Medicare benefit categories for digital health technologies.

Table 4.1. Cross-cutting Coverage Issues and Recommendations

Coverage Issue	Recommendations
<b>Need for regulatory modernization.</b> Medicare policies need modernization to harness the full potential of digital health technologies to help meet the challenges of improving care and reducing costs.	<b>11-A. CMS should take prompt steps to remove barriers to diffusion of digital health technologies presented by Medicare regulations, including:</b> <ul style="list-style-type: none"><li>• Conducting a regulatory and sub-regulatory review,</li><li>• Examining policy guidance, and</li><li>• Reviewing lessons learned from the pandemic response efforts.</li></ul>
<b>Lack of shared understanding and approach for cross-payer collaboration on uptake and diffusion of digital health technologies.</b> Digital health technologies cannot meet their full potential without cross-payer collaboration on the development and analysis of data on technologies’ impact on access, quality of care, and cost.	<b>11-B. HHS should establish an Inter-agency Task Force</b> to explore policies to improve access to and coverage for digital health technologies, including coordination across federal agencies and stakeholders.  <b>11-C. HHS should create a Public-Private Consortium to support the use and diffusion of digital health technologies.</b> Led by CMS and FDA, the Consortium would include payers, manufacturers/ developers, providers, patients, and trade associations. It would be tasked with developing common methodologies, metrics, and approaches to assessing the impact of digital health technologies on quality, health outcomes, and total cost of care. This could include the establishment of a framework for digital companies to use for generating evidence for payers.

Table 4.1. Cross-cutting Coverage Issues and Recommendations (cont.)

Coverage Issue	Recommendations
No Medicare benefit category for digital health technologies. Effective diffusion of digital health technologies is hampered by the slow modernization of Medicare’s benefit categories to encompass the state-of-the-art in clinical care.	11-D. In the absence of CMS action, the Congress should create a new benefit category(s) for digital health technologies to ensure that beneficiaries have prompt access to state-of-the-art clinical care.

SOURCE: CapView Strategies Analysis

Box 4.1 COVID-19 – The Role of Digital Health in Building a Nimble Medicare Program During the Public Health Emergency

The COVID-19 pandemic required unprecedented waivers of statutory provisions as well as regulatory actions to maintain access to inpatient and ambulatory services while protecting public health and safety. By allowing broader flexibility in the coverage and payment for digital health, CMS helped to maintain access to care across settings that would otherwise not have been possible during the pandemic. Policy actions ranged from providing payments to providers suffering financial losses, to waiving licensure and scope of practice requirements, as well as waivers of many rules governing telehealth payment.

A common theme across the policy changes enacted by CMS was the need to act quickly to increase access to care in the community—and digital health was a critical mechanism for connecting patients and providers. For instance, CMS waived requirements to allow Medicare providers to provide remote patient monitoring (RPM) services to first-time patients—which facilitated chronic disease management for many Medicare beneficiaries at home. Perhaps the best example of how digital health allowed the system to pivot to meet patient needs was in the area of telehealth. Far-reaching telehealth waivers allowed Medicare beneficiaries to consult with a broader range of providers from their homes, regardless of whether they resided in a rural area.

SOURCE: CapView Strategies Analysis

## END NOTES

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APPENDIX

ALL RECOMMENDATIONS IN THE REPORT\*

Table 2.1. DME Coverage Issues and Recommendations

Coverage Issue	Recommendations
Software as DME	
<p><b>Software, applications or algorithms on their own are not eligible to be covered as DME.</b></p> <p><b>Requirement that DME “primarily and customarily be used to serve a medical purpose” prohibits coverage of smart devices.</b> The requirement that the device must be used primarily to serve a medical purpose has created limited coverage of smart devices that could serve as a display function for medical applications covered as DME.</p> <p><b>Durability requirements.</b> CMS's definition of durability (minimum life requirement of three years) prohibits wider coverage of digital health technologies, including software and algorithms, and is too limited.</p>	<p><b>1-A. Create a regulatory pathway under DME for software (or an application)</b> that is “primarily and customarily” used to serve a medical purpose but can be used on any device that can satisfy the other durability requirements (e.g. laptops, home computers, smartphones, iPads, etc.) even if the device is not exclusively used for the software or application. The home computing device is not covered as DME or as a supply.</p> <p>When software serves the medical purpose, CMS should create the flexibility for its coverage with its use on home devices that meet durability requirements.</p> <p>(This recommendation divides the regulatory requirements for DME between the software and the home device used to display the software/application.)</p> <p><b>1-B. All other non-software components should be covered and coded independently as DME and/or supplies</b> and not bundled into the software supply allowance/payment rate. <b>If software is covered as DME, then major or clinically meaningful software updates should be covered as supplies</b> (routine updates are currently considered normal/routine servicing of digital health technologies).</p>

\* SOURCE: AdvaMed/CapView Strategies Analysis

**Table 2.1. DME Coverage Issues and Recommendations (cont.)**

Coverage Issue	Recommendations
<b>Software Integral to Otherwise Covered DME to be Covered as Supply</b>	
<b>Software as supply for otherwise covered DME.</b> CMS's non-recognition in regulations or sub-regulatory guidance of software as a supply that is critical for the adequate functioning of equipment otherwise covered as DME or implanted devices limits coverage and access.	<b>1-C. Cover software as a supply</b> when it is clinically meaningful and integral for the appropriate functioning of otherwise covered DME or when it provides new functionality. This will also include coverage for clinically meaningful software <b>upgrades</b> for software associated with the DME as a supply. However, all the components enabled and used with the software should be covered, coded and paid independently from the software as a supply.
<b>Breakthrough Technologies</b>	
<b>FDA breakthrough designations.</b> Coverage of breakthrough technologies is limited/slowed by CMS's process for recognizing digital health technologies within DME.	<b>1-D. Allow automatic assignment and payment</b> of HCPCS Level II codes for digital health technologies that are cleared or approved through FDA's Breakthrough Devices Program, used by a beneficiary in the home or community for a specified medical purpose as prescribed by a physician, and meet the other requirements under DME.
<b>Digital Therapeutics</b>	
<b>Software applications prescribed by physicians for use as therapy by a patient in their home are not currently covered as DME.</b>	<b>1-E. Create a regulatory pathway under DME to cover FDA cleared software as a medical device (SaMD)</b> which is for therapeutic use and is prescribed by a physician for use in a patient's home as DME.

**Table 2.2. Prosthetics and Orthotics Coverage Issues and Recommendations**

Coverage Issue	Recommendations
<b>Software Critical to Covered Prosthetic or Orthotic to be Covered as Supply</b>	
<p><b>Definition of software as supply in certain prosthetics or orthotics.</b> CMS's non-recognition in regulation or sub-regulatory guidance of software as a supply that is critical for the adequate or improved functioning of otherwise covered prosthetics or orthotics creates access issues.</p>	<p><b>2-A. Cover software as a supply</b> when it is integral for the appropriate functioning or provides new functionality to otherwise covered prosthetics (including implantables) or orthotics. This will also include coverage for clinically meaningful software upgrades for software associated with the prosthetic or orthotic as a supply. However, the devices enabled and used by the software should be covered and coded independently from the software.</p> <p><b>2-B. Cover clinically meaningful software upgrades as adjustments to covered prosthetics or orthotics.</b> For prosthetics or orthotics where a new software upgrade or functionality is available, the upgrade should be covered as an adjustment if prescribed by a physician.</p>
<b>Breakthrough Technologies</b>	
<p><b>FDA breakthrough designations.</b> Coverage of breakthrough technologies is limited or slowed by CMS's process for recognizing digital health technologies in prosthetics and orthotics.</p>	<p><b>2-C. Allow automatic assignment and payment</b> of HCPCS Level II codes for prosthetics and orthotics incorporating digital health technologies that are cleared or approved through FDA's Breakthrough Devices Program.</p>

**Table 2.3. Coverage Issues and Recommendations for MPFS**

Coverage Issue	Recommendations
<b>Breakthrough Technologies</b>	
<p><b>FDA breakthrough designation.</b> There is limited coordination between CMS and FDA, especially on the designation of breakthrough technologies and the subsequent use of this designation in Medicare coverage policy.</p>	<p><b>3-A. Allow automatic use/assignment of and payment</b> for Category III CPT codes for digital health technologies that are cleared or approved through FDA's Breakthrough Devices Program and are used by physicians.</p>

**Table 2.3. Coverage Issues and Recommendations for MPFS (cont.)**

Coverage Issue	Recommendations
<b>Coverage for New and Emerging Technologies</b>	
<p><b>Lack of a specific pathway for coverage of new and emerging FDA-approved technologies for physician use.</b> For new and emerging digital health technologies, it can be difficult to appropriately value and diffuse the technology without assigned codes or appropriate coverage in codes for current services.</p> <ul style="list-style-type: none"> <li>• <b>Valuing costs.</b> Appropriate methodology for valuing the costs associated with training and use of digital health technology is limited and may result in practice expenses not accurately reflecting all the digital health technology's costs.</li> <li>• <b>Valuing work.</b> Methodologies to value digital health technologies do not address the “work” the software does and the efficiencies it creates for physicians.</li> </ul>	<p><b>3-B.</b> For new and emerging FDA-approved digital health technologies that are used by physicians, <b>automatically assign a Category III CPT code and payment level for new technology or develop a modifier</b> to use with existing CPT codes when the digital technology is used with the service.</p> <p><b>3-C. Develop method to incorporate the value of software into CPT codes</b> to address practice expense and/or work intensity for relative value units (RVUs). The value of services delivered by a physician to interpret or act on new digital health technology information should be included in work RVUs. The value of the software used to address improvements and efficiency in patient care should be factored into practice expense RVUs.</p> <p><b>3-D. Develop a subscription-based payment approach for physician-prescribed digital technologies and continued clinical monitoring.</b> This methodology should pay for continued use during the physician-recommended period of time and allow for maintenance, monitoring and adjustments by the physician.</p>
<b>Digital Therapeutics</b>	
<p><b>No current coverage pathway or payment models exist for some digital therapies in MPFS.</b></p>	<p><b>3-E. Develop approaches for covering digital therapeutics, as a prescribed physician service.</b> A collaborative effort should include CMS working with the AMA, device manufacturers, and payers. This could include—but not be limited to—the subscription-based approach described in recommendation 3-D.</p>



Table 2.3. Coverage Issues and Recommendations for MPFS (cont.)

Coverage Issue	Recommendations
Remote Physiologic Monitoring	
<p><b>Use of remote physiological monitoring codes is currently limited.</b> The definition of “physiologic” in the introductory CPT language and the descriptors for remote physiological monitoring codes needs additional clarification. The term’s use and the type of items to which it applies are not fully defined and result in provider hesitation to utilize codes, fearing potential audits by CMS contractors investigating billing practices.</p>	<p><b>3-F. Provide guidance on the use of remote physiological monitoring codes for physicians</b>, including examples of the types of digital health technologies that could be covered under remote physiological monitoring codes. Consider clarifying use of codes for acute conditions and other opportunities to expand and incentivize use.</p> <p><b>3-G. Create a modifier</b> for specified digital health technologies used with existing care management codes such as CCM, transitional care management (TCM) and other care management codes, that improve the efficiency of care or augment the care plan—especially for monitoring of non-physiological metrics for care management.</p> <p>Additionally, as “E-Codes” are new codes in the MPFS, CMS should monitor their use and consider stakeholder feedback on improving use of these codes.</p> <p><b>3-H. Develop a new process, outside of the traditional CPT process, to recognize and pay for services that can be delivered through telehealth or remotely</b>, like device interrogation and programming that are currently described by in-person CPT codes. This could also include payment for software upgrades and adjustments.</p>

\* SOURCE: AdvaMed/CapView Strategies Analysis

**Table 2.4. Coverage Issues and Recommendations for Inpatient Hospitals**

Coverage Issue	Recommendations
<b>Breakthrough Technologies</b>	
<b>New Technology Add-on Payment (NTAP) pathway limited.</b> NTAP thresholds may be too high for digital health technologies. NTAP methodology does not accurately value the potential of digital health technologies. Although many technologies contribute to hospital cost savings and provide important care management tools, the cost of the digital health technology does not meet the cost threshold levels.	<b>4-A. Review NTAP requirements</b> with regard to digital health technologies or medical devices with software that provides new functionality, such as providing process improvements in care delivery to determine if changes should be made to encourage uptake, including the establishment of a lower cost threshold to receive payment.
<b>Incorporation into MS-DRGs.</b> Misassignment to DRGs and the two-to-three-year lag time for new cost-data inputs for DRGs limit the diffusion of digital health technologies.	<b>4-B. Implement a process to improve the assignment of MS-DRGs</b> when a new digital health technology is incorporated to more appropriately reflect costs and accuracy of payment and uptake.

**Table 2.5. Coverage Issues and Recommendations for Outpatient Hospital Setting**

Coverage Issue	Recommendations
<b>Improve transitional pass-through payments.</b> The transitional pass-through cost threshold may preclude some digital health technologies from diffusing to outpatient settings. Payments also need to better account for the potential value of the digital health technology. Many technologies contribute to hospital cost savings, but the cost of the digital health technology does not meet the cost threshold levels and therefore diffusion and uptake is limited.	<b>5-A. Modify transitional pass-through payment requirements</b> for digital health technologies to lower-cost thresholds.

**Table 2.5. Coverage Issues and Recommendations for Outpatient Hospital Setting (cont.)**

Coverage Issue	Recommendations
<p><b>Incorporation into APCs.</b> Misassignment of new technologies to lower-cost APCs is an issue for appropriate incorporation into the OPPS. Additionally, the two-to-three-year lag time in obtaining cost data from a new technology limits the diffusion of the digital health technology and its appropriate incorporation into an APC.</p>	<p><b>5-B. Implement a process to review APC assignments</b> and ensure new digital health technologies are appropriately valued and included in the APC determination.</p> <p><b>5-C. Implement a process to annually review HCPCS code value changes</b> to determine any necessary corresponding changes to APC assignments.</p>

**Table 2.6. Coverage Issues and Recommendations for ESRD PPS**

Coverage Issue	Recommendations
<p><b>Does not incentivize the use of services which may be provided via digital health technologies under bundled payments.</b> Neither the ESRD bundled payment nor the MCP include coverage for services provided that may incorporate digital health technologies.</p> <p><b>Face-to-face requirements for ESRD coverage.</b> To receive the MCP, a physician (or practitioner) must furnish at least one face-to-face visit per month to the beneficiary.</p>	<p><b>6-A. Include services associated with new technologies in the TPNIES</b> and clarify this inclusion in regulation.</p> <p><b>6-B. Clarify that physicians can bill RPM</b> codes used for monitoring of ESRD patients in addition to MCP.</p> <p><b>6-C. Make permanent changes to relax the requirement for face-to-face or in-person</b> visits for MCP payment, allowing phone and asynchronous visual visits to qualify.</p>

**Table 2.7. Coverage Issues and Recommendations for HHAs**

Coverage Issue	Recommendations
<b>Better explanation of definition of allowable administrative costs for new technologies for HHAs is needed.</b> While allowable RPM costs are new for HHAs, there are additional opportunities for HHAs to use digital health technologies in the provision and management of care for beneficiaries that are not currently part of the home health payment structure.	<b>7-A. Review HHA payment system</b> to evaluate opportunities to include digital health technologies other than RPMs as allowable administrative costs.

**Table 2.8. Coverage Issues and Recommendations for SNFs**

Coverage Issue	Recommendations
<b>SNF payment methodology does not include opportunities to incorporate digital health technologies.</b> The SNF payment methodology does not adequately value or incorporate digital health technologies into the payment system.	<b>8-A. Review SNF payment system to evaluate opportunities to encourage use of digital technologies</b> to improve care/reduce costs and allow digital health technologies to be included as allowable administrative costs—as in the case of home health services.

**Table 2.9. Coverage Issues and Recommendations for Digital Health Technologies in APMs**

Coverage Issue	Recommendations
<b>Lack of incentives for inclusion of digital health technologies into APMs.</b> Current APM participants may not be aware of the potential technologies available for incorporation into payment models. There are disincentives for providers to invest in digital health technologies—including the fact that APM benchmarks often do not reflect the costs of new technologies.	<b>9-A. Incentivize use and testing of digital health technologies in APMs</b> (e.g. through quality measures, bonus payments, or technical assistance to support implementation of technologies) and require CMS/CMMI to assess their impact on quality, patient outcomes, and health care costs.

**Table 2.9. Coverage Issues and Recommendations for Digital Health Technologies in APMs (cont.)**

Coverage Issue	Recommendations
<p><b>Methods to show value of digital health technologies for APMs are lacking.</b> Demonstration of the “value proposition” of the use of digital health technologies may be difficult because of lack of data and quality measures.</p>	<p><b>9-B. Develop a demonstration to evaluate opportunities for digital health technologies to improve quality and health outcomes and decrease Medicare costs.</b> For example, CMMI could test a temporary carve-out of the costs of new digital health technologies from the calculation of benchmarks and actual spending totals.</p>

**Table 3.1. Medicare Advantage Coverage Issues and Recommendations**

Coverage Issue	Recommendations
<p><b>Lack of standardized methods or data to demonstrate value.</b> Difficulty demonstrating the value of digital health technologies to MA plans may impede plan interest in indirect coverage.</p>	<p><b>10-A. Implement quality or other plan measures that assess use of digital health technologies</b> that improve patient care, efficiency.</p> <p><b>10-B. Create CMS workgroup</b> to help inform CMS on plans’ data requirements, opportunities for possible guidance on data requirements for coverage of digital health technologies, and to create a greater exchange of information on digital health technologies between plans and CMS. This could improve plan assessments of value and data for determining coverage.</p>
<p><b>Medicare national and local non-coverage decisions may impede inclusion of technologies in MA.</b> MA plans are unlikely to cover digital health technologies beyond national and local coverage decisions—even under supplemental benefits—without greater encouragement by CMS or demonstration of digital health technologies’ value.</p>	<p><b>10-C. Incentivize MA plans to provide and deploy new digital technologies</b> by issuing guidance addressing potential of supplemental benefits to improve quality and decrease cost.</p>

**Table 4.1. Cross-cutting Coverage Issues and Recommendations**

Coverage Issue	Recommendations
<p><b>Need for regulatory modernization.</b> Medicare policies need modernization to harness the full potential of digital health technologies to help meet the challenges of improving care and reducing costs.</p>	<p><b>11-A. CMS should take prompt steps to remove barriers to diffusion of digital health technologies presented by Medicare regulations, including:</b></p> <ul style="list-style-type: none"> <li>• Conducting a regulatory and sub-regulatory review,</li> <li>• Examining policy guidance, and</li> <li>• Reviewing lessons learned from the pandemic response efforts.</li> </ul>
<p><b>Lack of shared understanding and approach for cross-payer collaboration on uptake and diffusion of digital health technologies.</b> Digital health technologies cannot meet their full potential without cross-payer collaboration on the development and analysis of data on technologies' impact on access, quality of care, and cost.</p>	<p><b>11-B. HHS should establish an Inter-agency Task Force</b> to explore policies to improve access to and coverage for digital health technologies, including coordination across federal agencies and stakeholders.</p> <p><b>11-C. HHS should create a Public-Private Consortium to support the use and diffusion of digital health technologies.</b> Led by CMS and FDA, the Consortium would include payers, manufacturers/developers, providers, patients, and trade associations. It would be tasked with developing common methodologies, metrics, and approaches to assessing the impact of digital health technologies on quality, health outcomes, and total cost of care. This could include the establishment of a framework for digital companies to use for generating evidence for payers.</p>
<p><b>No Medicare benefit category for digital health technologies.</b> Effective diffusion of digital health technologies is hampered by the slow modernization of Medicare's benefit categories to encompass the state-of-the-art in clinical care.</p>	<p><b>11-D.</b> In the absence of CMS action, the <b>Congress should create a new benefit category(s)</b> for digital health technologies to ensure that beneficiaries have prompt access to state-of-the-art clinical care.</p>