CHAPTER 4

Paying for software technologies in Medicare

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Chapter summary

Software is increasingly important and pervasive in health care, driven by the availability of a multitude of technology platforms (e.g., personal computers, smartphones, network servers) and the growing ease of access and distribution (e.g., internet, cloud). Many types of clinical software, which include decision support intervention software, clinical risk modeling, and computer-aided detection (CAD), are increasingly available to providers. These technologies often perform data analysis of patients' diagnostic images. In addition, some software products incorporate artificial intelligence (AI), which uses algorithms or models to perform tasks and exhibits behaviors such as learning, making decisions, and making predictions. A subset of AI known as machine learning uses computer algorithms to learn through data to perform a task without being explicitly programmed; this type of AI has become an important part of a growing number of medical devices. While many of these technologies are new, certain types of clinical software, particularly CAD, have been used to aid or augment clinical decision-making for decades.

In this chapter, we discuss Medicare coverage of and payment for certain types of medical software that receive approval or clearance by the Food and Drug Administration (FDA), which the FDA has classified as software as a medical device (SaMD). We review the FDA's process for clearing

In this chapter

SaMD, examine Medicare's current coverage process and payments for SaMD under the payment systems for Part A and Part B services, and discuss issues that policymakers should keep in mind when considering paying for medical software in fee-for-service (FFS) Medicare.

The software that we discuss usually stands alone from hardware such as the machines used for MRI, computed tomography, and ultrasound scans, because the software performs functions that often categorize it as a medical device—software that is used for one or more medical purposes that diagnose or treat an illness or injury without being part of a hardware medical device. Even though the FDA classifies these technologies as SaMDs, for the purposes of this chapter we classify them into distinct categories:

- Software as a service (SaaS), which is algorithm-driven software that is either cleared or approved by the FDA to help practitioners make clinical assessments, including decision support intervention software, clinical risk modeling, and CAD. These technologies often rely on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment of a patient's condition. Examples of Medicare-covered SaaS include LumineticsCore, which detects diabetic retinopathy, and fractional flow reserve derived from computed tomography, which is used to diagnose and manage coronary artery disease.
- Prescription digital therapeutics (PDTs), which are software products that (1) receive market authorization (i.e., are either cleared or approved) by the FDA to manage or treat an injury or disease; (2) are prescribed by clinicians; (3) are typically administered by patients on a mobile phone, tablet, smartwatch, or similar technologies; and (4) primarily use software to diagnose or treat an illness or injury. Examples of PDTs include Parallel, which provides cognitive behavioral therapy on a patient's mobile phone or tablet to treat irritable bowel syndrome, and NightWare, a digital therapeutic that uses a smartwatch in the treatment of sleep disturbances.

We do not include remote monitoring technologies, health and wellness applications (apps), and health information technology systems in our definition of SaaS or PDT technologies.

The development of SaaS and PDTs is relatively new and evolving, and terminology that is used to refer to such technologies is generally not well established. In this chapter, we use the terms *SaaS* and *PDT* when discussing issues related to Medicare's coverage and payment because CMS, other

policymakers, and stakeholders often use this terminology when discussing such issues.

Before manufacturers of SaaS or PDT items can market a new product and seek Medicare coverage, they must comply with the requirements of the FDA, which applies the approval process for medical devices to the software products. The FDA uses three pathways to clear or approve SaaS or PDT items: premarket notification (PMN, also referred to as 510(k) clearance), De Novo classification, and premarket approval (PMA). Under the 510(k) pathway, the FDA clears a low- to moderate-risk device that a manufacturer demonstrates is "substantially equivalent," meaning that it is as safe and effective as another, similar device that is already on the market, referred to as the "predicate device." Under the De Novo pathway, the FDA clears a low- to moderate-risk medical device for which there is no previously FDA-approved predicate device. The PMA pathway is the most stringent FDA process of scientific and regulatory review. The FDA approves devices under the PMA pathway if there are sufficient clinical data to demonstrate that the device is safe and effective.

After receiving clearance or approval from the FDA, a manufacturer of a SaaS or PDT item can seek Medicare coverage for its product. Medicare covers items and services under Part A or Part B that are:

- included in a Medicare benefit category, such as inpatient hospital services and hospice care under Part A, and durable medical equipment (DME), immunosuppressive drugs, and outpatient services under Part B;
- not statutorily excluded (excluded services and supplies are, for instance, deemed medically unreasonable and unnecessary);
- reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, as indicated under the Social Security Act; and
- approved or cleared by the FDA, which is specific to Part B drugs, devices, and certain laboratory tests.

All items and services covered under Part A or Part B must also be covered in Part C of Medicare (Medicare Advantage (MA) except for hospice care and kidney acqusition costs, which are carved out of MA. In addition, all items and services (including SaaS and PDT items) that are covered under FFS Medicare are either separately payable (meaning that there is a distinct payment for the item or service) or packaged (meaning that the item or service is part of a larger payment bundle). The Medicare payment systems that cover SaaS and

PDT items include the outpatient prospective payment system (OPPS), the Medicare physician fee schedule, the inpatient prospective payment systems, the DME fee schedule, and the end-stage renal disease prospective payment system (PPS).

CMS has been deliberate in deciding whether to cover SaaS and PDT items that have FDA clearance or approval. Since 2018, FFS Medicare has covered and paid for SaaS in inpatient and outpatient hospital settings and in clinician offices. However, FFS Medicare generally does not cover PDTs because the Medicare statute lacks a separate benefit category for PDTs and the technology is not consistent with FFS Medicare's definition of DME, the Medicare benefit category that covers medical equipment and supplies used to treat beneficiaries' illness or injury in their residence. As of 2022, providers' use of the medical software that Medicare does cover has been relatively low.

A key issue facing FFS Medicare is how the program should pay for medical software that is generally separate from the medical device. Paying appropriately for medical software will mean finding a balance between promoting access to new technologies that meaningfully improve the diagnosis or treatment of beneficiaries and ensuring affordability for the Medicare program and the beneficiaries and taxpayers who finance it. For the hospital inpatient and outpatient PPSs and the end-stage renal disease PPS, the Commission has long supported larger payment bundles because they give providers opportunities to be flexible in the provision of care and incentives to use the most cost-efficient methods. By contrast, paying separately for software technologies can limit the competitive forces that generate price reductions among like services and can lead to overuse, which could have significant fiscal implications for FFS Medicare as the FDA clears or approves more and more such technologies over time. Unfortunately, for the various FFS Medicare fee schedules (e.g., physician fee schedule, DME fee schedule), in which the program generally pays for each service furnished, Medicare currently has few pricing tools that would help strike a balance between maintaining incentives for innovation and ensuring affordability for beneficiaries and taxpayers. The Commission will continue to deliberate on appropriate payment for software technologies under FFS Medicare. ■

Software is becoming increasingly important and pervasive in health care, driven by the availability of several technology platforms—such as personal computers, smartphones, and network servers—coupled with the ease of access and distribution using the internet or cloud. Many types of clinical software, which include decision support intervention (DSI) software, clinical risk modeling, and computer-aided detection (CAD), have become more and more available to providers. These technologies often perform data analysis of diagnostic images, especially MRI and computed tomography (CT) scans. In addition, some software products incorporate artificial intelligence (AI), which uses algorithms or models to perform tasks and to exhibit behaviors such as learning, making decisions, and making predictions. A subset of AI known as machine learning (ML) uses computer algorithms to learn through data to perform a task without being explicitly programmed; this type of AI has become an important part of an increasing number of medical devices (Food and Drug Administration 2022a). While many of these technologies are new, certain types of clinical software, particularly CAD, have been used to aid or augment clinical decision-making for decades (Centers for Medicare & Medicaid Services 2022b).

In this chapter, we discuss medical software that usually stands alone from hardware when it performs functions, such that the Food and Drug Administration (FDA) categorizes it as a medical device—software that clinicians use for one or more medical purposes that diagnose or treat an illness or injury without being part of a hardware medical device. We provide an overview of the FDA's process for clearing medical software; examine Medicare's current coverage process and payments for medical software under the payment systems for outpatient hospital services, acute inpatient hospital services, physicians and other health professionals, durable medical equipment (DME), and outpatient dialysis services; and enumerate issues that policymakers should consider in regard to Medicare payment for medical software.

Background

The FDA uses the term *software as a medical device* (SaMD) for the medical software that we discuss in this chapter. For the purposes of this chapter, we found it useful to separate SaMD into two broad categories:

- ***Software as a service:*** CMS refers to algorithm-driven software that is either cleared or approved by the FDA to help practitioners make clinical assessments (including DSI, clinical risk modeling, and CAD) as "software as a service" (SaaS). Some of these technologies rely on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment of a patient's condition (Centers for Medicare & Medicaid Services 2022b). Many of these technologies have been designed to augment medical imaging. Table 4-1 (pp. 142–144) provides examples of Medicare-covered SaaS.
- ***Prescription digital therapeutics:*** The definition of prescription digital therapeutics (PDTs) varies across manufacturers, payers, and other entities.[1] In this chapter, PDTs include software products that (1) receive market authorization (i.e., they are either cleared or approved) by the FDA to manage or treat an injury or disease; (2) are prescribed by clinicians; (3) are typically administered by patients on a mobile phone, tablet, smartwatch, or other similar technologies; and (4) primarily use software to diagnose or treat an illness or injury. Table 4-2 (p. 145) provides examples of PDTs.

Our discussion excludes medical software that does not fit the definition of SaaS or PDTs, such as remote monitoring technologies, health and wellness applications (apps), health information technology systems (such as patient portals and electronic health records), and telemedicine.[2]

The development of SaaS and PDTs is relatively new and evolving, and terminology that is used to refer to such technologies is generally not well established. SaaS is a term that CMS first defined in the calendar year 2023 outpatient prospective payment system (OPPS) rulemaking to pay for clinical decision software and algorithm-driven services that assist practitioners in making clinical assessments—particularly to perform data analysis of diagnostic images—under the OPPS. Stakeholders often use the term *PDT* to refer to prescription software applications that are generally furnished to a patient on a mobile device or internet application (Centers for Medicare & Medicaid Services 2022b, Digital Therapeutics Alliance 2023). Consequently, in this chapter, we use the terms *SaaS* and *PDT* when

TABLE 4–1

Examples of Medicare-covered software as a service that received market authorization from the FDA for use in the outpatient setting *(cont. next page)*

Name (manufacturer)	Description	FDA device type and approval	How device is paid under OPPS/PFS	OPPS/ PFS payment rate, 2024
Fractional flow reserve derived from computed tomography (FFRCT) (also referred to as Heart Flow) (HeartFlow Inc.)	Postprocessing software for the clinical analysis of previously acquired CT data for patients with coronary artery disease; it provides FFRCT—a mathematically derived quantity, computed from simulated pressure—velocity, and blood flow information obtained from a 3-D computer model generated from static coronary CT images	De Novo approval of a Class II AI/ML device	OPPS payment began in CY 2018. Since then, device is paid separately (not packaged) (CPT 75580). Under the PFS, the device is paid separately. Prior to CY 2023, item was carrier priced.* In CY 2023, CMS established (nationwide) RVUs for device.	$997 under OPPS; $903 under PFS*
EyeBox (Oculogica)	A device that measures and analyzes eye movements to help diagnose concussion within one week of head injury in conjunction with a standard neurological assessment of concussion; may be a stand-alone device or implemented as a software app on a smartphone or tablet	De Novo approval of a Class II AI/ML device	OPPS payment began in CY 2020. Prior to CY 2023, item was packaged into payment with any separately payable service provided during the same visit. Since CY 2023, item is paid separately (CPT 0615T). Under the PFS, device is separately paid and carrier priced.**	$122 under OPPS; carrier priced under PFS**
LumineticsCore (formerly known as IDx-DR) (Digital Diagnostics)	A device that incorporates an adaptive algorithm to evaluate ophthalmic images to identify retinal diseases or conditions	De Novo approval of a Class II AI/ML device (Breakthrough)***	OPPS payment began in 2018 ("bridge payment") with status indicator Q1 (packaged into payment with any separately payable service provided during the same visit). Since CY 2021, item is paid separately (CPT 92229). Under the PFS, device is separately paid. Prior to CY 2022, device was carrier priced.** In CY 2022, CMS established (nationwide) RVUs for device.	$58 under OPPS; $41 under PFS

discussing issues related to Medicare's coverage and payment because CMS, other policymakers, and stakeholders often use this terminology when discussing such issues. By contrast, we use the FDA-defined term *SaMD* when discussing the FDA's process to clear and approve both types of technologies.

The FDA's process for clearing and approving medical software

Before medical software manufacturers can market a new product and seek Medicare coverage, they must comply with the requirements of the FDA, which is

TABLE 4–1

Examples of Medicare-covered software as a service that received market authorization from the FDA for use in the outpatient setting *(cont. next page)*

Name (manufacturer)	Description	FDA device type and approval	How device is paid under OPPS/PFS	OPPS/ PFS payment rate, 2024
LiverMultiScan (Perspectum)	An MR diagnostic device software application for noninvasive liver evaluation that enables the generation, display, and review of 2-D MR medical image data and pixel maps for MR relaxation times; the software then sends the provider a quantitative metric report of the patient's liver fibrosis and inflammation	510(k) approval of an AI/ML Class II device	OPPS payment began in CY 2021. Prior to CY 2023, device was packaged when provided with MRI. Device paid separately since CY 2023: CPT 0648T (device not provided with diagnostic MRI), CPT 0649T (device provided with diagnostic MRI). Under the PFS, device is separately paid and carrier priced.**	$950 for CPT 0648T and 0649T under OPPS; carrier priced under PFS**
Virtual Nodule Clinic (referred to by CMS as "LCP" (lung cancer prediction)) (Optellum)	A device that applies an algorithm to a patient's CT scan to produce a raw risk score for a patient's pulmonary nodule; the physician uses the risk score to quantify the risk of lung cancer and help determine whether to refer the patient to a pulmonologist	510(k) approval of an AI/ML Class II device	OPPS payment began in CY 2022; during that year, the device was packaged when provided with CT scan. Beginning CY 2023, device paid separately: CPT 0721T (device not provided with CT scan), CPT 0722T (device provided with CT scan). Under the PFS, device is separately paid and carrier priced.**	$650 for CPT 0721T and 0722T under OPPS; carrier priced under PFS**
Quantitative magnetic resonance cholangiopan-creatography (Perspectum)	A device that performs quantitative assessments of the biliary tree and gallbladder using a proprietary algorithm that produces a 3-D reconstruction of the biliary tree and pancreatic duct and provides precise quantitative information on biliary tree volume and duct metrics	510(k) approval of an AI/ML Class II device	OPPS payment began in CY 2022; during that year, the device was packaged when provided with MRI. Beginning CY 2023, device paid separately: CPT 0723T (device not provided with MRI), CPT 0724T (device provided with MRI). Under the PFS, device is carrier priced.**	$950 for CPT 0723T and 0724T under OPPS; carrier priced under PFS**
Cleerly Labs (Cleerly Inc.)	Postprocessing web-based software application that analyzes coronary images acquired from CT angiographic scans to help determine treatment for patients suspected of having coronary artery disease; the software output includes visual images of coronary arteries and distance and volume measurements of the lumen wall, vessel wall, and plaque	510(k) approval of an AI/ML Class II device	OPPS payment began in 2022. Since 2022, device paid separately (CPT 0625T).** Under the PFS, device is separately paid and carrier priced.**	$950 under OPPS; carrier priced under PFS**

TABLE 4–1

Examples of Medicare-covered software as a service that received market authorization from the FDA for use in the outpatient setting *(cont.)*

Name (manufacturer)	Description	FDA device type and approval	How device is paid under OPPS/PFS	OPPS/ PFS payment rate, 2024
XV Lung Ventilation Analysis Software (4DMedical)	Provides detailed information on regional lung function using CT images; this technology quantifies regional lung ventilation and ventilation heterogeneity	510(k) approval of an AI/ML Class II device	OPPS payment began in 2024 and device is separately paid: CPT 0807T (device not provided with CT), CPT 0808T (device provided with CT). Under the PFS, device is separately paid and carrier priced.**	$299 for CPT 0807T and 0808T under OPPS; carrier priced under PFS**
Icobrain (Icometrix)	Quantitative MRI analysis of the brain with comparison to prior MR studies, including lesion identification, characterization, and quantification, with brain volume(s) quantification and/or severity score (when performed), data preparation and transmission, interpretation, and report	510(k) approval of an AI/ML Class II device	OPPS payment began in 2024 and device is separately paid: CPT 0865T (service not provided with MRI), CPT 0866T (service provided with MRI). Under the PFS, device is separately paid and carrier priced.**	$234 for CPT 0865T and 0866T under OPPS; carrier priced under PFS**
EchoGo Heart Failure (Ultromics)	Postprocessing of echocardiography that uses AI to detect heart failure with preserved ejection fraction	510(k) approval of an AI/ML Class II device (Breakthrough)***	OPPS payment began in 2024 and device is separately paid (HCPCS C9786).	$285 under OPPS; no billing code assigned to device under PFS

Note: FDA (Food and Drug Administration), OPPS (outpatient prospective payment system), PFS (physician fee schedule), AI/ML (artificial intelligence/machine learning), CY (calendar year), CT (computed tomography), CPT (Current Procedural Terminology), 3-D (three-dimensional), RVU (relative value unit), MR (magnetic resonance), MRI (magnetic resonance imaging), 2-D (two-dimensional), HCPCS (Healthcare Common Procedure Coding System). PFS payment rate reflects the rate that CMS implemented as of March 9, 2024.
*CMS uses different methods for setting payment rates under the OPPS and the PFS, resulting in different payment rates for the same service under these two payment systems.
**CMS has not established RVUs for service/item under the PFS. Instead, carriers (Medicare administrative contractors) establish payment amounts for this service, generally on an individual case basis.
***To qualify for the FDA's Breakthrough designation, a device must provide more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition and meet one of the following criteria: The device must represent a breakthrough technology, there must be no approved or cleared alternatives, the device must offer significant advantages over existing approved or cleared alternatives, or the availability of the device is in the best interest of patients.

Source: MedPAC analysis of CMS's final rules for physician services and OPPS, 2018–2024, and the FDA's Medical Devices 510(k) and De Novo databases.

responsible for regulating medical devices. The FDA clears or approves medical software with one or more device functions and generally refers to them as "software as a medical device" (SaMD), which includes SaaS technologies and PDTs.[3] (Another type of medical software with a device function—software in a medical device—is outside the scope of this chapter. The text box (p. 146) explains key differences between software as a medical device and software in a medical device.)

The FDA uses a risk-based regulatory system (created by the 1976 Medical Device Amendments) to classify devices as Class I, Class II, or Class III based on the level of control needed to assure their safety and effectiveness at a high level (Food and Drug

TABLE 4–2

Examples of prescription digital therapeutics that have been granted market authorization by the FDA

Software name	Function	Device type	Approval pathway
BlueStar and BlueStar Rx	Analyzes and reports glucose test results for individuals with diabetes and supports medication adherence	Class II	510(k)
NightWare	Reduces sleep disturbances related to nightmare disorders or nightmares from post-traumatic stress disorder	Class II Breakthrough*	De Novo
Parallel (also called Mahana IBS)	Delivers CBT for the treatment of irritable bowel syndrome	Class II	510(k)
reSET	Delivers CBT for the treatment of substance use disorder (substance use disorder)	Class II	De Novo
reSET-O	Delivers CBT in the treatment of substance use disorder (opioid use disorder)	Class II Breakthrough*	510(k)
Somryst	Delivers CBT in the treatment of chronic insomnia	Class II	510(k)

Note: FDA (Food and Drug Administration), CBT (cognitive behavioral therapy).
*To qualify for the FDA's Breakthrough designation, a device must provide more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition and meet one of the following criteria: the device must represent a breakthrough technology, there must be no approved or cleared alternatives, the device must offer significant advantages over existing approved or cleared alternatives, or the availability of the device is in the best interest of patients.

Source: MedPAC analysis of FDA's Medical Devices 510(k), De Novo, and Breakthrough databases.

Administration 2018b). The higher the class, the more risk a device poses to the consumer. The riskier a device is, the more stringent the regulatory pathway for market authorization.

The FDA's regulatory pathways for medical devices

Under its authorities in the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA), the FDA regulates the safety and effectiveness of medical devices. The FFDCA defines a medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals." In general, the FDA regulates SaaS technologies and PDTs (with certain exceptions) as medical devices.[4]

The FDA uses a three-tier system to categorize medical devices by risk.

- Devices in Class I, which is the lowest tier in the FDA's system, are low risk. Examples include bandages, handheld surgical instruments, and nonelectric wheelchairs. Class I devices are not intended for use in supporting or sustaining life or to be of substantial importance in preventing impairment to human health, and they must not present a potential unreasonable risk of illness or injury (Food and Drug Administration 2018a).
- Class II devices are those that pose a moderate risk and are subject to special controls (which might include performance standards, postmarket

SaMD versus SiMD: What is the difference?

Software as a medical device, or SaMD, differs from what the Food and Drug Administration (FDA) considers software in a medical device, or SiMD, which is defined as software that is integral to the function of a hardware medical device.[5] Examples of SiMD include software that controls the inflation and deflation of a blood pressure cuff and software used in a closed-loop control of a pacemaker (Schroeder 2023).

The main distinction between SiMD and SaMD is that SiMD must be necessary for a hardware medical device to achieve its intended use, whereas SaMD does not have to be necessary for a hardware device to achieve its intended use. Both SaMD and SiMD may be deployed on a mobile platform, which the FDA refers to as a "mobile medical app" and for which the agency has released specific guidance (Food and Drug Administration 2022d). ■

surveillance, and patient registries, among others) (Food and Drug Administration 2018b). Examples of Class II medical devices include CT scanners and infusion pumps for intravenous medications.

- Medical devices in Class III, the most stringent regulatory class, pose the highest risk. These devices are intended to support or sustain human life or prevent health impairment, or are devices that might present an unreasonable risk of illness or injury for which general and special controls are insufficient to provide reasonable assurance of the device's safety and effectiveness (Food and Drug Administration 2018b). Examples include pacemakers and deep-brain stimulators.

The FDA uses the following pathways to clear or approve medical devices: premarket notification (PMN, also referred to as 510(k) clearance), De Novo classification, and premarket approval (PMA) (Food and Drug Administration 2018d).

- Under the 510(k) pathway, the FDA clears a low- to moderate-risk medical device that a manufacturer demonstrates is "substantially equivalent," meaning that it is as safe and effective as another, similar device that is already on the market, which is referred to as the "predicate device" (Food and Drug Administration 2022e, Food and Drug Administration 2021). Devices cleared through the 510(k) pathway are not required to conduct clinical trials.
- Under the De Novo pathway, the FDA clears low- to moderate-risk medical devices for which there is no FDA-approved predicate device. The sponsor may need to furnish clinical data to demonstrate that the benefits of the device outweigh the risks (Food and Drug Administration 2022c).
- The PMA pathway is the most stringent FDA process of scientific and regulatory review and is required for Class III devices. The FDA approves devices if there are sufficient clinical data to demonstrate that the device is safe and effective (Food and Drug Administration 2019).

FDA approval of software technologies

As technology has advanced, software has become increasingly important to medical devices, to the point where software alone can be considered a medical device. The FDA defines SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device" (Food and Drug Administration 2024b). The industry has also referred to SaMD as "stand-alone software," "medical device software," and/or "health software" (Food and Drug Administration 2018c). While SaMD is sometimes embedded in medical hardware, the software itself performs the function and is not dependent on the hardware. This software may work on general-purpose (nonmedical) computing platforms; may be used in combination with other products, including medical devices; and may interface

Coverage of services in Medicare Advantage

Under Part C, Medicare Advantage (MA) plans are required to provide the same set of benefits that are available under fee-for-service (FFS) Medicare except hospice and kidney acquisition costs, which are carved out of MA and covered under FFS Medicare (exclusive of plans in the CMS Innovation Center's MA Value-Based Insurance Design Model) and certain services associated with clinical trials under Medicare's Clinical Trials Policy for MA enrollees. However, MA plans are permitted to furnish extra benefits (such as prescription digital therapeutics not covered by FFS Medicare) that FFS enrollees cannot access without purchasing additional health insurance coverage or paying for such services out of pocket. ■

with other medical devices or other general-purpose hardware and software that provide input to SaaS. That is, SaMD can be used across a range of technology platforms, including mobile medical apps, commercial "off the shelf" platforms, and virtual networks. The FDA released its first guidance on premarket submission for SaMD in 2005 and released updated guidance in 2023 based on its experience evaluating the safety and effectiveness of medical software (Food and Drug Administration 2023, Food and Drug Administration 2005). Recent years have seen an increase in the number of AI/ML-enabled software devices that the FDA has reviewed predominantly through 510(k) and De Novo pathways as Class II devices (Food and Drug Administration 2022a).

The software technologies listed in Table 4-1 (pp. 142–144), which include AI/ML-enabled software and DSI software,[6] and the PDTs listed in Table 4-2 (p. 145) are examples of FDA-approved SaMD.[7] The FDA generally clears both types of technology as Class II devices (meaning that they are low to moderate risk) under either the 510(k) or De Novo pathways (Table 4-1, pp. 142–144, and Table 4-2, p. 145).

Medicare's coverage process

Medicare covers a broad range of health care services under its Part A, Part B, Part C, and Part D programs, included in Title XVIII of the Social Security Act. For Part A and Part B services furnished in FFS Medicare, the statute requires that the program cover items and services that are included in a Medicare benefit category, are not statutorily excluded, and are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Although the statute sets forth the broad categories of benefits covered by Medicare, neither the statute nor the regulations provide an all-inclusive list of the specific items and services that are reasonable and necessary.

Medicare coverage decisions for most Part A and Part B services are made at both the national level (by CMS) and local level (by Medicare administrative contractors, or MACs). However, many services do not require an explicit coverage determination, such as services paid through CMS's prospective payment mechanisms. Medicare is not required to consider comparative clinical effectiveness evidence in the coverage process, and the program lacks explicit statutory authority to consider a service's cost-effectiveness or value when making coverage decisions. Under Part C of Medicare, Medicare Advantage plans are required to cover the same items and services covered under Part A and Part B of Medicare with the exception of hospice care and kidney acquisition costs (see text box on coverage of services in Medicare Advantage).

Neither SaaS nor PDT technologies are explicit Medicare benefit categories in the statute. To date, Medicare has covered SaaS technologies when the services met Medicare's coverage criteria. However, PDTs have generally not been covered by Medicare

TABLE 4–3 **Overview of Medicare's coverage process for Part A and Part B items and services**

	Type of coverage policy	Who develops the policy	Where the policy applies
Existing billing code or bundled payment system	Explicit policy may not be necessary if service is in existing code or bundle	CMS	Nationwide (binding on all contractors)
NCD	Explicit	CMS	Nationwide (binding on all contractors)
Program memos and manuals	Explicit	CMS	Nationwide (binding on all contractors)
LCD	Explicit policy that can apply to an item or service that existing NCDs do not address or policy that further defines an NCD	Medicare's contractors (medical directors)	Contractor's regional jurisdiction; policy for a given service can vary across regions
Claim-by-claim adjudication (i.e., no LCD or NCD)	Explicit	Medicare's contractors (medical directors)	Contractor's regional jurisdiction; policy for a given service can vary across regions

Note: NCD (national coverage determination), LCD (local coverage determination).

Source: MedPAC analysis of Title XVIII of the Social Security Act and CMS program manuals and guidance.

because they do not meet coverage criteria (i.e., because such technologies are not consistent with FFS Medicare's definition of durable medical equipment, the Medicare benefit category that covers medical equipment and supplies used to treat beneficiaries' illness or injury in their residence).

Medicare coverage for Part A and Part B items and services

According to regulation and statute, Medicare covers Part A and Part B items and services that meet the following requirements:

- They must be included in a Medicare benefit category, such as inpatient hospital services and hospice care under Part A and durable medical equipment, immunosuppressive drugs, and outpatient services under Part B (services in hospital outpatient departments, physician offices, and other sites of ambulatory care).[8] Over time, Medicare's benefit categories have been expanded. For example, beginning in 2008, the Medicare Improvements for Patients and Providers Act of 2008 gave Medicare the authority to cover selected new preventive services.
- They must not be statutorily excluded, such as services and supplies that are medically unreasonable and unnecessary or that are denied because they are bundled or included in another service's basic allowance (Centers for Medicare & Medicaid Services 2022a).
- They must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (Social Security Administration 2023). CMS considers a service reasonable and necessary

if the service is safe and effective, not experimental or investigational, and appropriate for beneficiaries.

- They must be approved or cleared by the FDA, specific to Part B drugs, devices, and certain laboratory tests.[9]

There are several ways for items and services to be covered under FFS Medicare (Table 4-3). For many Part A and Part B items and services, Medicare coverage occurs without the need for an explicit coverage policy. If an item or service falls under a Medicare benefit category and can be reimbursed on the basis of an existing billing code or a bundled payment system (e.g., the inpatient prospective payment systems), Medicare might cover it without an explicit coverage policy.

An initial step toward coverage of new items and services (particularly items and services seeking separately billable payment rather than inclusion under a bundled payment system) is generally to receive a billing code. Codes are assigned by two entities and used by Medicare and other payers' committees (see text box, p. 150, for additional information about assigning billing codes to medical services). CMS decides whether items and services that have been assigned a new billing code are among the types of health care benefits described in the Medicare statute and are reasonable and necessary for a beneficiary's treatment and therefore eligible for Medicare payment.[10]

When an explicit coverage determination is required, CMS and MACs develop policies at the national and regional level, respectively, to determine whether a service meets one of the covered benefit categories and is reasonable and necessary, in which case it is covered. MACs develop the majority of explicit coverage policies. These policies, referred to as "local coverage determinations" (LCDs), determine coverage of specific medical services that apply only in the contractor's regional jurisdiction. LCDs must be consistent with the statute, regulations, and national policies for coverage, payment, and coding.

In addition to the LCD process, CMS develops coverage determinations for specific medical services that apply nationwide through the national coverage determination (NCD) process.[11] The process of developing both LCDs (that are new or have undergone major revision) and NCDs provides opportunities for public comment, and both types of coverage determinations are available in the Medicare Coverage Database on CMS's website. Outcomes of the coverage process include (1) Medicare coverage of an item or service with no restrictions, (2) coverage for beneficiaries with certain clinical conditions or when furnished by certain providers or facilities, (3) leaving the coverage determination to the discretion of the MACs, or (4) Medicare not covering the service.

The national and local processes are not the only means by which Medicare develops and publishes coverage policies. Medicare's provider manuals and program memoranda include policies that affect the coverage of services. CMS develops these policies, which apply nationwide to all contractors.

Coverage of software technologies

Based on statutory and regulatory text, Medicare coverage for new technologies requires that the technology:

- has received marketing authorization from the FDA;
- fits into a covered Medicare benefit category (e.g., inpatient care, outpatient services, DME, diagnostic tests); and
- meets other statutory requirements in Section 1862 of the Social Security Act, including being reasonable and necessary for the treatment of an illness or injury and not being statutorily excluded from coverage.

Although neither SaaS technologies nor PDTs are explicit Medicare benefit categories in the statute, Medicare covers such services under two circumstances:

- Medicare will generally cover and pay for a service that can be reimbursed on the basis of an existing billing code or a bundled payment system (e.g., through the inpatient prospective payment systems), unless existing local or national coverage determinations define or restrict when Medicare will pay for providing the service.
- For a service assigned a new billing code, Medicare will determine whether the service is included in a Medicare benefit category (described in the Medicare statute) and therefore eligible

Assigning billing codes to medical services

Medicare's payment systems for claims are highly automated and rely on billing codes for beneficiaries' diagnoses and treatments to identify the medical services that clinicians furnish. Medical services, including procedures, drugs, and devices, are identified on the basis of five-digit billing codes that are assigned by two entities. The American Medical Association (AMA) assigns and maintains Level I of the Healthcare Common Procedure Coding System (HCPCS), referred to as the CPT (Current Procedural Terminology), codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. CMS assigns and maintains HCPCS Level II codes for drugs, biologicals, nondrug and nonbiological items, supplies, and other services that are not included in the Level I CPT codes.

Recently, the AMA's CPT Editorial Panel provided guidance on how they classify various artificial intelligence/machine learning software applications into one of three categories: assistive, augmentative, or autonomous (American Medical Association 2024). The categorization is based on the service provided to the patient and the work performed by the software on behalf of the clinician. These categories differ with respect to what the service does (e.g., detect clinically relevant data vs. interpret such data) and the extent of direct clinician involvement (Table 4-4). ■

TABLE 4–4

Overview of the AMA's categorization of software applications

	Service classification		
Service characteristic	**Assistive**	**Augmentative**	**Autonomous**
Function of service	Detects clinically relevant data	Analyzes and/or quantifies data to yield clinically meaningful output	Interprets data and independently generates clinically meaningful conclusions
Whether the service provides independent diagnosis and/or management decision	No	No	Yes
Whether the service analyzes data	No	Yes	Yes
Whether the service requires clinician interpretation and report	Yes	Yes	No

Note: AMA (American Medical Association).

Source: Adapted from the AMA Current Procedural Terminology Appendix S: Artificial Intelligence Taxonomy for Medical Services & Procedures.

for Medicare payment (as long as the service is reasonable and necessary for a beneficiary's treatment). This process may or may not require an explicit coverage determination (Government Accountability Office 2003).

The SaaS items listed in Table 4-1 (pp. 142–144) have each been assigned their own billing code and fit into an existing benefit category; thus, Medicare covers them. For example, the American Medical Association issued two new Healthcare Common Procedure Coding System (HCPCS) codes for quantitative magnetic

resonance cholangiopancreatography, a SaaS item that performs quantitative assessment of the biliary tree and gallbladder. This service is paid for in outpatient settings; Medicare has not issued either a local or national coverage determination for this service.[12]

By contrast, the PDTs listed in Table 4-2 (p. 145) are generally not covered by Medicare because (1) such technology is not consistent with Medicare's definition of DME (the Medicare benefit category that covers medical equipment needed at home to treat a beneficiary's illness or injury) and (2) the statute lacks a benefit category for prescription medical software.

How Medicare pays for software technologies

Medicare uses three methods to pay for SaaS that meets Medicare's coverage criteria under Part A or Part B:

- separate payment under an existing billing code (i.e., a shared billing code that includes more than one product);
- separate payment under a billing code unique to the product;
- payment under a broader bundled payment. Under certain bundled payment systems (e.g., inpatient and end-stage renal disease prospective payment systems (PPSs)), Medicare uses a temporary new technology payment policy for qualifying technologies, typically for a two- to three-year period, and then includes them in a bundled payment.

FFS Medicare payment for SaaS technology began in 2018 with coverage of fractional flow reserve derived from CT (FFRCT), which clinicians use in outpatient settings to analyze data from CT angiography scans. Since then, Medicare has covered and paid for other SaaS technologies in clinicians' offices and hospital outpatient departments (HOPDs). However, stakeholders have expressed concern that Medicare's payment systems do not yet account for most of the medical devices that involve AI/ML technology. Stakeholders have also noted the differences between the physician fee schedule (PFS) and outpatient prospective payment system (OPPS) in Medicare payment policies for SaaS items (Frank et al. 2023). CMS has not created national payment rates under the PFS for most SaaS items, and payment is "carrier priced," meaning payment is determined by MACs, generally case by case. In contrast, there are specific payment rates for each SaaS item covered under the OPPS. For hospital inpatient care, FFS Medicare also covers and pays for software as part of the broader bundled payment made for each hospital stay. In a few cases, software products have received new technology add-on payments.

In this section, we provide an overview of payment for medical software under the payment systems for hospital outpatient services, acute care hospital inpatient services, physician and other health professional services, DME, and outpatient dialysis services.

Payment for medical software under Medicare's hospital outpatient prospective payment system

SaaS items are a small part of hospital outpatient care for FFS Medicare beneficiaries, but their presence in HOPDs is growing. In the rulemaking that set 2023 payment rates in the OPPS, the payment system for most services provided in HOPDs, CMS devoted much discussion to coverage of and payment for SaaS items under the OPPS (Centers for Medicare & Medicaid Services 2022b). Because SaaS items are becoming more important in this setting, how CMS sets OPPS payment rates for SaaS items is an increasingly relevant issue.

Under the OPPS, CMS classifies each service as either separately payable or packaged; for most services covered under the OPPS, the decision is clear cut. Separately payable services are generally major items that are relatively costly or are the focal point of the HOPD visit, such as a CT scan, chemotherapy administration, or insertion of a device. By contrast, packaged services are those that CMS considers ancillary, supportive, dependent, or adjunctive to a separately payable service, such as injection of a low-cost drug during an emergency department visit. For separately payable services, the OPPS provides a single payment for a bundle that includes the separately payable service and the packaged services and ancillary items that are provided with that separately payable service. That is, there is an explicit payment

for the separately payable service, but this payment also includes an implicit payment for the packaged services and packaged ancillary items. The OPPS has several categories of packaged services. One of these categories is "add-on" codes, which are for services that, when provided, always occur in conjunction with a separately payable service.[13] Examples of services with add-on codes are debridement of subcutaneous tissue beyond 20 square centimeters and tissue transfer for each 30 square centimeters beyond the initial 60 square centimeters.

The first SaaS item covered under the OPPS was FFRCT, which has the trade name HeartFlow; clinicians use it to measure coronary artery disease using data from CT angiography scans. CMS added FFRCT as a covered OPPS service in 2018. Since then, CMS has granted covered OPPS status to several SaaS items (Table 4-1, pp. 142–144).

When CMS added FFRCT as a covered OPPS service, the agency had to determine whether it should be separately payable or packaged. FFRCT is unusual because it has some attributes that suggest it should be packaged and other attributes that suggest it should be separately payable. CMS decided that it was appropriate to pay separately because the analytics are performed by an entity separate from the provider of the related CT angiography (a FFRCT technician who performs computer analytics off-site), which the agency determined made FFRCT different from a typical packaged service that always occurs in conjunction with a separately payable service and therefore is paid using an add-on code.

Since CMS began covering SaaS items under the OPPS in 2018, the agency has granted separately payable status to most covered SaaS items (Table 4-1, pp. 142–144). However, for some SaaS items, the AMA created two CPT codes for each item. Clinicians use all of these SaaS items to analyze data from an MRI or CT scan. However, sometimes clinicians use these SaaS items to analyze data from an already existing imaging scan, and other times they use the items immediately as part of an imaging scan. For 2022, in the former case, CMS considered the SaaS item a stand-alone service and made it separately payable; in the latter case, CMS considered the SaaS item an add-on service, so it was packaged. However, in the rule-making process for 2023 OPPS payment rates, CMS reevaluated the SaaS items that the agency had considered add-on services in 2022. CMS concluded that the services described by these SaaS items were not consistent with the agency's definition of typical add-on codes that are packaged under the OPPS. CMS found that the cost of the SaaS items exceeded the cost of the imaging services with which they would be billed and determined that the SaaS items are separate and distinct services rather than services that are ancillary, supportive, dependent, or adjunctive to a separately payable service, which are CMS's standards for packaged services.[14] After this reassessment, CMS changed the status of these codes to separately payable. Consequently, all SaaS items have been separately payable services under the OPPS since 2023.

Through 2022, seven SaaS items were separately payable under the OPPS, and three more were packaged services (CMS reclassified them as separately payable in 2023). Of the seven SaaS items that were separately payable under the OPPS in 2022, only HeartFlow (CPT code 0503T) had volume and spending of significant magnitude (8,665 uses and $8.4 million). LiverMultiScan (CPT code 0648T) and Cleery Labs (CPT code 0625T) had volume of less than 100 uses and spending less than $50,000. The other four SaaS items that were separately payable had no volume and no spending in 2022.

Payment for medical software under Medicare's hospital inpatient prospective payment systems

Under the IPPS, Medicare pays acute care hospitals a bundled rate for each FFS beneficiary's hospital stay. That payment is generally intended to cover all services provided by the hospital during the inpatient stay. Each case is assigned to a Medicare severity–diagnosis related group (MS–DRG), and Medicare's payment for the case is adjusted by a relative weight that reflects the relative costs of caring for the average case assigned to the MS–DRG. Because the cost of a new technology might not initially be reflected in the data that are used to establish the MS–DRG relative weights, a manufacturer of a new device or drug can apply for a new technology add-on payment (NTAP) for the first two to three years that a product is on the market.[15] After that time, the payment for the new technology is bundled into the payment rates for the applicable MS–DRGs.

To qualify for an NTAP under the IPPS, a new technology must meet three criteria: (1) it must be new, that is, not substantially similar to existing technologies; (2) it must be high cost relative to the MS–DRG payment amount; and (3) it must represent a substantial clinical improvement. New technologies that receive certain designations from the FDA (including products designated as Breakthrough Devices or qualified infectious disease products (QIDPs) or products approved by the FDA under the limited population pathway for antibacterial and antifungal drugs (LPAD)) need only demonstrate that they meet the cost criterion (criterion 2) and do not need to demonstrate that they are different from existing technologies (criterion 1) or that they represent a substantial clinical improvement (criterion 3).

For products that qualify for an NTAP, Medicare's payment is generally the lesser of 65 percent of (1) the cost of the new technology or (2) the amount by which the estimated costs of the case exceed the standard MS–DRG payment. Drug products with QIDP or LPAD status receive a higher payment percentage, 75 percent.

When CMS first considered whether an NTAP should be granted for an AI/ML–enabled medical device with the application for ContaCT in the fiscal year (FY) 2021 IPPS rulemaking, there were a number of questions about whether and how the agency should consider these types of software products under the existing NTAP process. Several issues arose concerning how to judge whether a software product is not substantially similar to existing technologies (NTAP criterion 1) and how to estimate cost per case for a software product that is sold to hospitals on a subscription basis (which affects the cost criterion (NTAP criterion 2) and the maximum NTAP amount for the product). (A more detailed discussion of these NTAP issues is included in the text box (pp. 154–155).)

In total, six products that received market authorization from the FDA and include software or machine learning have received NTAPs. Two of these products, ContaCT and Caption Guidance, have had their NTAP status sunset and are bundled into the payment rates for the applicable MS–DRGs. For fiscal year (FY) 2024, four new products receive NTAPs:

- Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) system: The tibial extension implant contains electronics and software, used with the Zimmer Persona Personalized Knee System. This technology collects kinematic data pertaining to a patient's gait and activity level following total knee arthroplasty using internal motion sensors (3-D accelerometers and 3-D gyroscopes). The collected kinematic data from the implanted medical device are intended as an adjunct to standard of care and physiological parameter measurement tools applied or used by the physician during the course of patient monitoring and treatment postsurgery. The maximum NTAP for a case involving the use of the CTE with CHIRP system is $850.85 for one knee or $1,701.70 for two knees for FY 2024.
- Ceribell Status Epilepticus Monitor: This medical device system is composed of proprietary software and two cleared, proprietary products—a single-use signal acquisition headband (the Ceribell electroencephalogram (EEG) headband) and a recorder (the Ceribell pocket EEG). The software uses a machine learning model to analyze EEG signals to detect features indicative of electrographic status epilepticus (ESE) to provide more effective diagnosis of ESE in adult patients at risk for seizure. The maximum NTAP for a case involving the use of the Ceribell Status Epilepticus Monitor is $913.90 for FY 2024.
- EchoGo Heart Failure 1.0: This automated machine learning–based decision support system is indicated as a diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography. When used by an interpreting clinician, this device provides information that may be useful in detecting heart failure with preserved ejection fraction. EchoGo Heart Failure 1.0 takes as input an apical four-chamber view of the heart that has been captured and assessed to have an ejection fraction of at least 50 percent. The maximum NTAP for a case involving the use of EchoGo Heart Failure 1.0 is $1,023.75 for FY 2024.
- SAINT neuromodulation system: This technology is a noninvasive repetitive transcranial magnetic stimulation system that identifies an individualized target and delivers navigationally directed repetitive magnetic pulses to that target located within the left dorsolateral prefrontal cortex (L–DLPFC) to

New technology add-on payments under the hospital inpatient prospective payment systems

As CMS has considered manufacturers' applications for new technology add-on payments (NTAPs) for software products that involve artificial intelligence (AI) and machine learning (ML), the agency has worked through a number of issues about how the general NTAP framework applies to these types of products.

Under the inpatient prospective payment systems (IPPS), for the first two to three years the product is on the market, new technologies can receive add-on payments if they meet three criteria:

1. They are new—that is, not substantially similar to existing technologies.
2. They are high cost relative to the Medicare severity–diagnosis related group (MS–DRG) payment amount.
3. They represent substantial clinical improvement.

New devices that receive the Breakthrough Device designation from the Food and Drug Administration (FDA) are deemed to meet criteria 1 and 3 and need only to demonstrate that they meet the cost criterion.

CMS uses several criteria to determine whether a product is new. In general, a product is considered substantially similar to an existing technology—not new—if it meets all of the following conditions: (1) it uses the same or similar mechanism of action as an existing technology to achieve a therapeutic outcome, (2) the technology has been assigned to the same MS–DRG as that existing technology, and (3) the technology involves treatment of the same or similar type of disease and patient population as the existing technology.

When CMS first considered ContaCT's application for an NTAP (the first AI/ML–enabled software to receive an NTAP), questions arose about how the newness criterion would apply to software. One key

(*continued next page*)

treat major depressive disorder in adult patients who have not achieved satisfactory improvement from prior antidepressant medication in the current episode. The SAINT neuromodulation system consists of hardware devices (for example, stimulator with treatment coil and neuro-navigation) designed to deliver SAINT therapy to a targeted area within the L–DLPFC. The system also includes cloud software that identifies the personalized target. The maximum NTAP for a case involving use of the SAINT neuromodulation system is $12,675 for FY 2024.

In FY 2022, two SaaS items had NTAP status under the IPPS—Caption Guidance and ContaCT. Both technologies had appreciable volume and NTAPs in 2022. Caption Guidance had volume of 813 uses and $1.1 million in NTAPs; ContaCT had volume of 98,000 uses and NTAPs of $72.4 million. As noted above, under the IPPS, NTAPs are the lesser of 65 percent of the average cost of the technology or the amount by which the costs of the case in which the technology is used exceed the MS–DRG payment amount. In many instances, hospital use of Caption Guidance and ContaCT resulted in $0 in NTAPs, which indicates that the cost of the case was less than the MS–DRG payment rate.

Payment for medical software under Medicare's physician fee schedule

Medicare pays for the services of physicians and other health professionals furnished to FFS beneficiaries based on a list of services and their payment rates, called the Medicare physician fee schedule (PFS). Under the PFS, most payment rates are based on relative

New technology add-on payments under the hospital inpatient prospective payment systems (cont.)

question pertained to defining the mechanism of action for software. CMS expressed concern about whether use of AI, an algorithm, or software—items that are not tangible—could be used to identify a unique mechanism of action. Additionally, CMS concluded that ContaCT did not use the same or a similar mechanism of action to achieve a therapeutic outcome when compared with existing (FDA-approved) treatments; consequently, ContaCT met the newness criterion. CMS also indicated that the agency would continue to consider issues related to defining unique mechanisms of action for these types of software technologies, including how updates to AI, an algorithm, or software would affect an already approved technology or a competing technology; whether software changes for an already approved technology could be considered a new mechanism of action; and whether an algorithm improved by competing technologies would represent a unique mechanism of action if the outcome were the same as that of an already approved new AI technology. These issues surrounding the mechanism of action are not relevant for products that receive the Breakthrough Device designation since they are deemed not substantially similar to existing technologies for purposes of the NTAP.

Another question concerns how to measure cost per patient for software that hospitals purchase on a subscription basis. With subscription software, the cost per patient depends in part on the volume of patients for whom the software is used: The higher a hospital's volume of patients, the lower its cost per patient. CMS has questioned whether per patient cost of subscription software should be estimated based on data for hospitals currently subscribing to the software or for all IPPS hospitals. To date, CMS has used the estimated cost per patient based on NTAP applicants' analyses of estimated cost for subscriber hospitals.[16] Another question CMS has raised is whether the maximum NTAP amount for a software product should be updated (if the product continues to be eligible for an NTAP in the future) based on the most recent subscriber data. ■

weights, called relative value units (RVUs), which account for the relative costliness of the inputs used to provide clinician services: clinician work, practice expense (PE), and professional liability insurance.

CMS pays for devices considered SaaS items under the PFS as long as the technology fits under an existing benefit category (e.g., diagnostic services under Section 1861(s) of the Social Security Act) and meets all other coverage criteria. However, the agency has faced methodological challenges in determining the PE RVUs for these new technologies (see text box on payment for software under the PFS, p. 156). Consequently, instead of establishing RVUs, CMS has generally paid carrier-set prices for the SaaS items listed in Table 4-1 (pp. 142–144), meaning that Medicare's administrative contractors set the payment amount for such services, generally on a case-by-case basis after reviewing the documentation. CMS established RVUs for two services (in 2022, 2023, and 2024) by basing the SaaS items' RVUs on a similar service. In 2022, FFS Medicare spending for SaaS under the PFS was low; of the services listed in Table 4-1, FFRCT had the highest spending (about $2.5 million).

CMS does not pay for the SaaS items defined as PDTs listed in Table 4-2 (p. 145) under the PFS because such technologies do not fall into an existing Medicare benefit category.

Payment for medical software under Medicare's durable medical equipment fee schedule

Medical equipment prescribed by a clinician and needed at home to treat a FFS beneficiary's illness or

Determining practice expense for software as a service under Medicare's physician fee schedule

Practice expense (PE) payments cover the direct and indirect costs that clinicians incur in operating a practice. Under the Medicare physician fee schedule (PFS), CMS determines relative value units (RVUs) for a given service (including technologies considered software as a service (SaaS)) using two types of PE—direct PE and indirect PE. Direct PE includes the nonphysician clinical labor, disposable medical supplies, and medical equipment that are typically used to provide a service and are determined for each service through a bottom-up approach in which component costs (e.g., equipment and supply costs) are aggregated at the service level.

Indirect PE includes the costs associated with administration, rent, and other services that cannot be attributed to any specific service, and so CMS uses a top-down approach to allocate the pool of total indirect PE across all PFS services. This complex, multistep process includes a formula that considers the physician work and clinical labor costs associated with the service and the direct PE costs associated with that service adjusted by a ratio that reflects the cost structures of the specialties that tend to bill for that service. For most specialties, CMS derives the specialty-specific indirect percentage from survey data (the Physician Practice Expense Information (PPI) Survey) conducted in 2007 and 2008 (reflecting 2006 data) on indirect PEs incurred per hour worked. Indirect PE plays a significant role in how overall PE is distributed across services.[17]

CMS has not adopted the RVU recommendations from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) for SaaS items because of methodological issues in determining a service's PE costs. For example, the agency did not adopt the RUC's recommendation for direct PE costs of $25 "per click" for LumineticsCore, an AI system that autonomously diagnoses diabetic retinopathy (Table 4-1, pp. 142–144) because (1) CMS considered this cost a service fee and, as such, a form of indirect PE, and (2) CMS asserted that this cost is appropriately captured via the indirect PE methodology rather than counted as a separate direct PE input (Centers for Medicare & Medicaid Services 2020a). CMS has either carrier-priced the SaaS technologies listed in Table 4-1 or set the RVUs of the technology based on a similar service (i.e., to address the lack of data on resource costs for a new service assigned to a new billing code, CMS cross-walks the resource costs of an existing service to the new service).

Historically, CMS has treated most medical software and licensing and analysis fees as indirect PE costs (not as a direct PE cost like the RUC treats such fees) because these costs are not individually allocable to a particular patient for a particular service.[18] CMS acknowledges the concerns from some stakeholders that treating software as an indirect PE cost does not account for newer technologies (e.g., SaaS) that rely primarily on analysis/licensing fees with minimal costs associated with medical equipment (and not included in the equipment costs) (Centers for Medicare & Medicaid Services 2023b). However, CMS has said that treating medical software that is not associated with using physical equipment to furnish the service (e.g., SaaS) as a direct cost under the current PE methodology could inadvertently result in allocating too much indirect PE costs to a given service (because direct PE costs are used to allocate indirect PE).

The age of the survey data used to allocate indirect PE costs also raises concerns about potentially misallocating indirect costs. The source of the specialty-specific indirect percentage was the PPI Survey, which was last administered in 2007 and 2008, when emerging technologies that rely primarily on software, licensing, and analysis fees with minimal costs in medical equipment and hardware were not routinely used. According to CMS, such SaaS costs are not well accounted for in the PPI Survey. ■

injury is covered under the DME benefit. DME must meet all five of the following conditions:

- can withstand repeated use;
- has an expected life of at least three years (for items classified as DME after January 1, 2012);
- is primarily and customarily used to serve a medical purpose;
- generally is not useful to an individual in the absence of an illness or injury; and
- is appropriate for use in the home.[19]

Some examples of DME covered by Medicare include walkers, wheelchairs, and home oxygen equipment and related supplies. Medicare also covers supplies that are necessary for the effective use of DME (e.g., oxygen in oxygen tanks). For items not subject to competitive bidding, Medicare pays for DME using a fee schedule.[20] Medicare pays for DME on a HCPCS basis using either a shared billing code (i.e., multiple similar items paid under a single billing code) or a billing code unique to the technology.

Medicare pays for medical software that is embedded in a device (and thus integral to a device's function) as long as the device meets the DME five-part definition. By contrast, the DME benefit generally does not pay for medical software that resides on beneficiaries' personal devices (e.g., personal computers, smartphones, tablets, laptops, or other similar technologies) because these items do not meet the DME five-part definition since personal devices are considered nonmedical (i.e., such devices are not primarily and customarily used to serve a medical purpose). The following are examples of the types of devices with software that Medicare pays for under the DME benefit:

- Speech-generating devices (speech aids) consisting of devices or software that generate speech and are used by beneficiaries with a severe speech impairment. However, Medicare's definition of a speech-generating device does not pay for personal devices that may be programmed to perform the same functions or specific features not related to "functional speaking," such as hardware or software used to create documents or play games. Such features would not meet the current definition of DME (e.g., primarily and customarily used to serve a medical purpose) (American Speech-Language-Hearing Association 2023, Centers for Medicare & Medicaid Services 2023c).
- Continuous glucose monitors. The DME benefit permits use of personal devices as long as such devices are used in conjunction with a stand-alone receiver or insulin infusion pump that Medicare classifies as DME to display glucose data. That is, there must be a durable component capable of displaying the trending of the continuous glucose measurements in addition to the display of such results on personal devices (Centers for Medicare & Medicaid Services 2023a).
- PDTs in which the medical software and the device in which it is housed are integral to each other. For example, Medicare covers RelieVRx, a virtual reality cognitive behavioral therapy system for treatment of chronic low back pain. The components of the Class II device that received FDA market authorization include a headset, breathing amplifier, and preloaded software; the device can be used only for treatment of the specified clinical indication.

Medicare does not pay for FDA-approved medical software that is furnished solely on personal devices (e.g., smartphones, laptops) because personal devices do not primarily and customarily serve a medical purpose. Table 4-2 (p. 145) provides examples of PDTs that Medicare currently does not cover. In a DME payment determination for several PDTs (reSET, reSET-O, and Somryst) that provide cognitive behavioral therapy or a neurobehavioral intervention, CMS concluded:

> Smartphones and computers are generally useful to individuals in the absence of illness or injury and are therefore not DME. . . . Digital therapies or computer software are housed on non-medical devices like smartphones or computers and the equipment and software as a whole are not DME. (Centers for Medicare & Medicaid Services 2022a)

Although CMS does not cover PDTs under the DME benefit, the agency established a new HCPCS Level II code A9291 effective April 1, 2022: "Prescription digital behavioral therapy, FDA cleared, per course of treatment" (Centers for Medicare & Medicaid Services 2022a).

Payment for medical software under Medicare's end-stage renal disease payment system

Since 2011, Medicare pays dialysis facilities using a PPS bundle comprised of the services—dialysis equipment, supplies, and labor—that are furnished to FFS patients during a given dialysis treatment, including end-stage renal disease (ESRD) drugs and clinical laboratory tests (for which facilities previously received separate payments). Medical software is covered and paid for as part of the prospective payment bundle.

Since 2020, there has been an add-on payment—the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES)—for ESRD-related equipment and supply items that meet the following six criteria:

- They have been designated by CMS as a renal dialysis service.
- They are new, meaning within three years beginning on the date of the FDA marketing authorization.
- They are innovative, meaning they meet the substantial clinical improvement criteria.
- They have complete HCPCS Level II code applications submitted for items and services that are DME, orthotics, prosthetics, and supplies.
- They are not capital-related assets, except for such assets that are home dialysis machines.
- They are commercially available by January 1 of the year in which the payment adjustment would take effect.

For a two-year period, Medicare pays 65 percent of a qualifying technology's cost using information from invoices and other relevant sources. Thereafter, the piece of equipment or supply is included in the PPS payment bundle, without any change to the ESRD PPS base rate.

As of June 2023, no applicants had submitted a TPNIES application for a SaaS item. Since January 2022, one ESRD equipment item has qualified for a TPNIES—the Tablo Hemodialysis System, a home hemodialysis machine.[21]

Obtaining good value for Medicare

New software technologies are of growing importance in the delivery of health care. According to Daniel and colleagues:

> AI systems and applications are ubiquitous and are embedded into almost every industry today, including health care. AI-enabled DxSS [diagnostic support software], as a subset of CDS [clinical decision support], has the potential to equip clinicians, staff, patients, and others with the knowledge they need to enhance overall health and improve outcomes by supporting their decision-making processes, helping them arrive at a correct diagnosis faster, reducing unnecessary testing and treatments otherwise resulting from misdiagnosis, and reducing the amount of pain and suffering by facilitating earlier treatment initiation. (Daniel et al. 2019)

The Commission is in the initial stages of considering how Medicare should pay for medical software. However, the Commission has long maintained that the goal of Medicare payment is to obtain good value for the program's expenditures, which means maintaining beneficiaries' access to high-quality services while encouraging efficient use of resources. Anything less does not serve the interests of the taxpayers and beneficiaries who finance Medicare through their taxes and premiums. Regarding other new services (drugs and biologicals), the Commission has said that Medicare should establish payment in a way that (1) promotes access to new technologies that meaningfully improve the diagnosis or treatment of beneficiaries, (2) ensures technologies' affordability for beneficiaries and taxpayers, and (3) creates incentives for the development of new technologies that lead to substantial clinical improvement (as opposed to incentives for developing technologies that have only marginal benefits) (Medicare Payment Advisory Commission 2023).

A key issue facing Medicare is how the program should pay for medical software that is generally separate from the medical device. For the IPPS, OPPS, and dialysis sectors, the Commission has repeatedly said that paying separately for items and services instead of including them in each sector's PPS bundle:

- undermines the integrity of payment bundles;
- limits the competitive forces that generate price reductions among like services;
- can lead to overuse (to the extent clinically possible); and
- shifts financial burden from providers to the Medicare program, beneficiaries, and taxpayers.

Across all settings, paying separately for SaaS items could have implications for Medicare. According to CMS, "the number of FDA approved or cleared 'machine learning' or 'AI' clinical software programs has rapidly increased in the past few years" (Centers for Medicare & Medicaid Services 2022b).

In its comment letter on the 2023 OPPS proposed rule, the Commission responded to CMS's proposal (which was later finalized) to classify all SaaS items as separately payable services. The Commission focused on a payment approach that would broadly apply to SaaS items, including payment strategies for these services across care settings. The Commission recognized the need to ensure beneficiaries' access to new technologies that improve outcomes while preserving the incentives for efficiency that can be achieved within FFS Medicare's PPSs. Combining a primary service and related ancillary items, including items and services with a similar function, into a single payment unit encourages efficiency because the combination of inputs used to treat a beneficiary determines whether the provider experiences a financial gain or loss. Broader bundles also foster competition among similar items and services, which generates pressure on manufacturers and suppliers to reduce prices. Use of broader payment bundles in the OPPS would make the system more like the IPPS. With respect to the OPPS, the Commission has long supported larger payment bundles because they provide hospitals with opportunities to find flexibility in providing care and incentives to use the most cost-efficient methods. Consequently, the Commission advised CMS to continue seeking ways to increase the amount of packaging and the extent to which SaaS and other items and services can be bundled based on encounters or episodes of care.

Providers make decisions about the use of software in many aspects of their operations, and they optimize these decisions given their own circumstances and the existing technologies and contractual relationships already in place. In such complex situations, bundled payment, rather than separate payment for specific software products, creates more desirable incentives, encouraging providers to choose technologies based on what is most effective in their own operations and not creating or distorting financial incentives for items that may not be optimal in terms of efficacy or efficiency.

Specific to the software technologies discussed in this chapter, the broader the bundle, the more likely Medicare is to pay for the services in an efficient manner. For hospital services and other episodic bundles, technology may be expected to decrease the cost of services, eliminate the need for add-on payments, and promote competition in a mix of human capital and technology-driven services to promote more efficient care delivery (Miller 2023). The use of larger payment bundles can also provide useful signals about which SaaS items are effective and improve efficiency of care. To the extent that MA plans and providers holistically consider whether a service (in this case, software technology) improves patient outcomes and service delivery, per person capitated payments in MA may be more advantageous than payment on a per unit basis in FFS Medicare.

Because of the advantages inherent in bundled payment, paying for new software technologies under the various FFS Medicare fee schedules (e.g., the PFS and DME fee schedules), in which the program pays for each service furnished, raises several concerns. For items and services that are separately billable, Medicare has few pricing tools that would help the program strike a balance between maintaining incentives for innovation and ensuring affordability for beneficiaries and taxpayers. In addition, manufacturers set prices based on what they believe the U.S. health care market will bear for items and services that FFS Medicare pays separately under their own billing codes. Paying for software technologies on a per use basis could therefore lead to overuse of such technology and may have significant fiscal implications for Medicare, particularly as the FDA clears or approves more and more such technologies over time. To improve incentives and maintain affordability under the fee schedules, policymakers could consider adjusting a service's payment rate using a modifier for new

software technologies, such as one based on the extent to which the technology reduces a clinician's work time (Miller 2023). Other approaches include setting a payment rate for new software technologies based on:

- A market price (likely to be unrelated to the clinical value of the product) that is determined by the manufacturer's pricing decisions (such as the average price realized by manufacturers for sales to most purchasers, net of rebates, discounts, and price concessions). CMS generally uses such an approach to establish an initial payment rate for a new technology. Over time, CMS usually updates the initial payment rate through the rate-setting methods in the applicable FFS payment system.
- A new product's net clinical benefit compared with the standard of care, an approach that would aim to balance affordability for beneficiaries and taxpayers with an appropriate reward for manufacturer innovation.

As Medicare pays for software technologies, some have questioned how to ensure that the technologies improve health outcomes. In a cross-sectional analysis of clinical studies of FDA-authorized PDTs (as of November 29, 2022), Kumar and colleagues found important limitations in the rigor of evidence. For example, 40 percent of PDTs had clinical studies that were not blinded, and the clinical studies frequently excluded older adults and people not proficient in English (Kumar et al. 2023). To ensure that the technologies improve health outcomes, Medicare could require that a manufacturer of a SaaS/PDT provide evidence that its product results in a clinically meaningful improvement compared with the current standard of care for Medicare beneficiaries. Alternatively, for a technology that lacks clear evidence that it has a positive effect on care, Medicare could apply a coverage with evidence development policy that links a service's national coverage to participation in an approved clinical study or to the collection of additional clinical data. The goal of coverage with evidence development is to expedite early beneficiary access to innovative technology while ensuring that patient safeguards are in place.

Moving forward, the Commission will continue to monitor the use of software technologies in FFS Medicare and among other payers, including MA plans and commercial payers. The Commission will also continue to deliberate on appropriate payments for such software under FFS Medicare. ■

Endnotes

1 The definition of PDTs, also referred to as digital therapeutics (DTx), is ambiguous because there is no international consensus on what PDTs are (Wang et al. 2023). DTx was first defined in 2015 as "evidence-based treatments from the field of behavioral medicine that are delivered online" (Sepah et al. 2015). The Digital Therapeutics Alliance, the leading international organization on digital therapeutics, states that these treatments "deliver to patients evidence-based therapeutic interventions that are driven by high quality software programs to treat, manage, or prevent a disease or disorder. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes" (Digital Therapeutics Alliance 2023).

2 CMS does pay for certain remote monitoring technologies. For example, under the physician fee schedule, beginning in 2018, CMS began making separate payments for the services described by CPT code 99091, which paid for collection and interpretation of physiologic data digitally stored and/or transmitted to the practitioner. Beginning in 2019, CMS began paying for additional new remote physiologic monitoring codes.

3 The FDA does not regulate the practice of medicine, including clearing or approving medical services (Food and Drug Administration 2024a).

4 The 21st Century Cures Act of 2016 excludes certain categories of software functions from the definition of a device (e.g., certain types of clinical support software and health administrative software). In addition, according to FDA guidance, the agency intends to exercise enforcement discretion (meaning it does not intend to enforce requirements under the FFDCA) for software functions that may meet the definition of a medical device but pose lower risk to the public (such as software functions that provide periodic educational information and software functions that use a checklist of common signs and symptoms to provide a list of possible medical conditions and advice on when to consult a health care professional) (Food and Drug Administration 2022d).

5 According to draft guidance issued by the FDA, the agency defines SiMD as "software that meets the definition of a device in section 201(h) of the Act and is used to control a hardware device or is necessary for a hardware device to achieve its intended use. Typically, SiMD is embedded within or is part of a hardware device" (Food and Drug Administration 2023).

6 AI/ML-enabled medical software items are defined by the FDA as "software incorporating artificial intelligence (AI), and specifically the subset of AI known as machine learning (ML)" (Food and Drug Administration 2022a). Because of the ability of AI/ML software to learn from real-world feedback, continually improve performance, and advance the precision of medical care, it is a subset of medical software receiving rapid research and development (Gottlieb and Silvis 2023).

7 The 21st Century Cares Act (CCA) removed certain types of DSI software from the definition of a medical device. Under the CCA, DSI software is considered "nondevice [DSI]" and not subject to the FDA's device regulation if the software meets all four of the following criteria: (1) software does not acquire or analyze medical images; (2) software function displays or analyzes medical information normally communicated between clinicians; (3) software function provides recommendations to a clinician rather than a specific directive; and 4) software function provides the basis of the recommendations so that the clinician does not rely primarily on any recommendation to make a decision (Food and Drug Administration 2022b).

8 Most categories are defined in Sections 1812, 1832, and 1861 of the Social Security Act.

9 The FDA recently finalized a policy (through the rule-making process) that, effective July 5, 2024, certain laboratory developed testing services are medical devices under the FFDCA, including when the manufacturer of such products is a laboratory.

10 CMS notifies contractors whether each new code can be covered and, based on this information, whether Medicare's automated claims processing systems pay or deny claims submitted with one of these codes (Government Accountability Office 2003).

11 A small subset of NCDs links a service's national coverage to participation in an approved clinical study or to the collection of clinical data. This policy is referred to as "coverage with evidence development," and its goal is to expedite early beneficiary access to innovative technology while ensuring that patient safeguards are in place.

12 Three MACs issued billing and coding guidance for this service.

13 A separately payable service does not always have an add-on code provided with it, but an add-on code is always provided with a separately payable service.

14 For most services covered under the OPPS, CMS estimates the costs as hospital charges reported on claims that are adjusted to approximate costs. In 2022, however, the SaaS items for which CMS was considering whether to package or pay separately had not yet been on the market long enough for CMS to collect reliable charge data. In these situations, CMS usually relies on data from the manufacturer of the SaaS item to estimate costs.

15 Each year, CMS establishes the relative weights for the MS–DRGs by estimating the average cost per case for each MS–DRG relative to the average cost per case for all MS–DRGs. In this process, CMS takes claims data from two years prior and cost-to-charge ratios from the Medicare cost reports to estimate the average cost per case for each MS–DRG. Because CMS develops the relative weights for a given year using claims data from two years prior, the weights do not incorporate the potential cost of new technology developed in the interim period.

16 In response to CMS's questions about whether software cost estimates should be based on all IPPS hospitals or only subscriber hospitals, the manufacturer of ContaCT analyzed cost per patient using both approaches and indicated that the cost per case would be higher if they extrapolated to all IPPS hospitals rather than if they used data for subscriber hospitals (Centers for Medicare & Medicaid Services 2020b).

17 Indirect PE constitutes a substantial portion of the RVUs allocated across the PFS, accounting for roughly one-third (approximately $30 billion) of PFS payments in fiscal year 2019 (Burgette et al. 2018).

18 CMS has in some cases considered software a direct PE cost. For example, in 2019, the agency included the sheer wave elastography software (ED060) as a direct PE input for elastography (CPT codes 76981–76983), a type of imaging. In this case, the sheer wave elastography software was an additional resource cost added to the general ultrasound room (EL015) equipment, without which the service cannot be performed.

19 Section 1861 of the Social Security Act includes certain items defined as DME, including iron lungs, oxygen tents, hospital beds, certain wheelchairs, and—for beneficiaries with diabetes—blood-testing strips and blood glucose monitors.

20 Fee schedule rates are largely based on supplier charges from July 1986 through June 1987 (updated for inflation) and on information such as unadjusted list prices for products introduced after that time period.

21 Medical software is a component of this hemodialysis machine. The Tablo System is composed of (1) a console with integrated water purification, on-demand dialysate production, and a touchscreen interface; (2) a proprietary single-use pre-strung cartridge; and (3) the Tablo Connectivity and Data Ecosystem. As of January 1, 2022, CMS established HCPCS E1629: "Tablo hemodialysis system, for the billable dialysis service" (Centers for Medicare & Medicaid Services 2021).

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