MEDPAC

Advising the Congress on Medicare issues

Paying for software technologies in Medicare

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Presentation roadmap

1. Definition and characteristics of SaaS and PDTs
2. Statutory requirements for Medicare coverage and payment
3. Payment for software technologies in Medicare's payment systems
4. Preliminary results from interviews with developers and a commercial insurer
5. Discussion

Note: SaaS (software as a service), PDT (prescription digital therapeutic).

Previous work on paying for medical software technologies

- Chapter in June 2024 report to the Congress
- Technologies covered under FFS Medicare payment systems
- Requirements for FDA approval or clearance
- Requirements for Medicare payment:
  - More technologies are meeting Medicare payment requirements
- Use and payments for medical software under FFS Medicare payment systems:
  - CMS has had difficulties setting PFS payment rates

Note: FFS (fee-for-service), FDA (Food and Drug Administration), FFS (fee-for-service), PFS (physician fee schedule).

Medical software technologies

- Software that is used or prescribed by clinicians for one or more medical purposes *without being part of a hardware medical device*
- Two types of medical software technologies: Software as a service (SaaS) and prescription digital therapeutics (PDTs)
- SaaS: Algorithm-driven software that can be assistive, augmentative, or autonomous:
  - E.g., AI-driven software that analyzes images of the eye taken by a retinal camera to diagnose diabetic retinopathy
- PDTs: Software applications that treat an illness or injury and are delivered on beneficiaries' personal devices:
  - E.g., cognitive behavioral therapy to treat insomnia

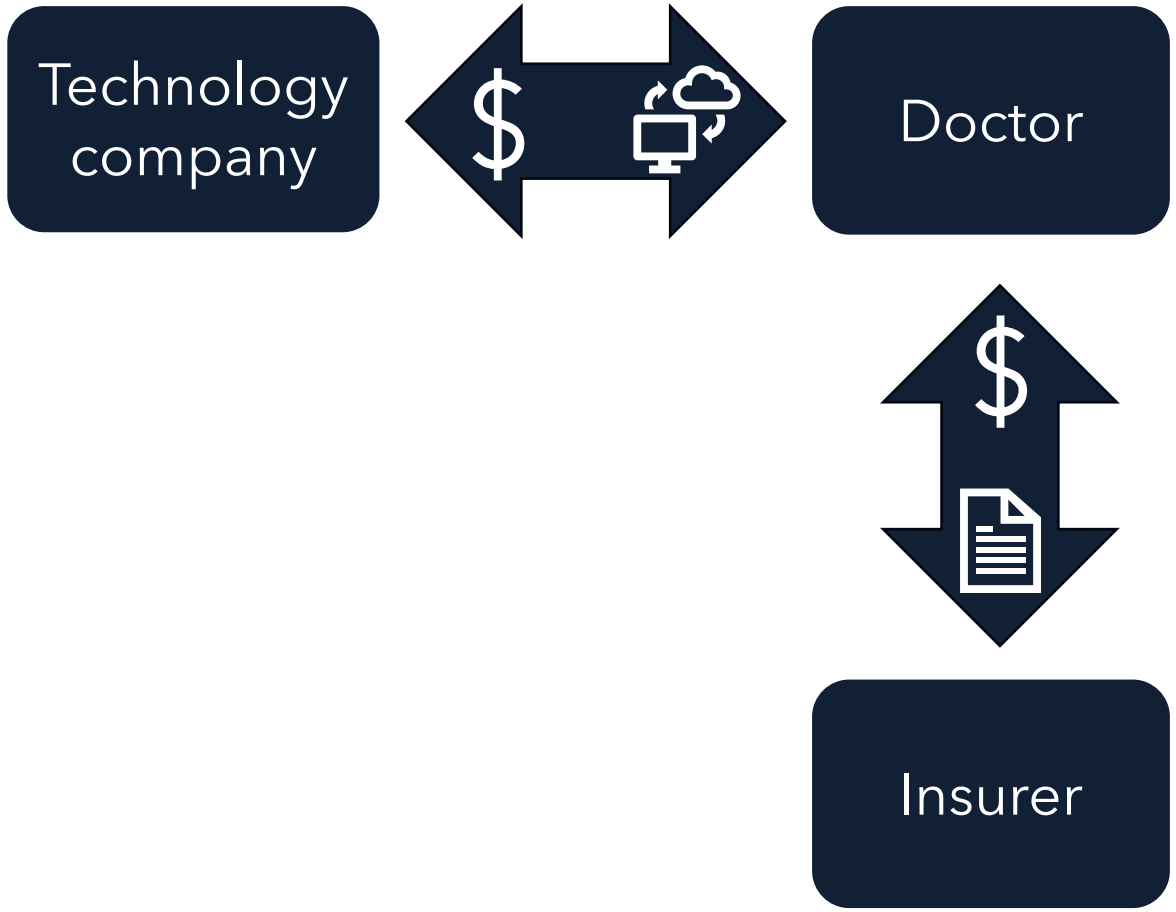
Note: AI (artificial intelligence).

FDA approval or clearance of medical software technologies

- FDA uses a 3-tier system to categorize medical devices by risk (Class I, Class II, Class III)
- FDA classifies most SaaS and PDTs as Class II devices:
  - Pose a moderate risk
  - Subject to special controls such as performance standards, postmarket surveillance, or patient registries
- As Class II devices, SaaS and PDTs are typically cleared through the 510(k) or De Novo pathways:
  - 510(k): Technology is "substantially equivalent," meaning it is similar to a technology already on the market (predicate)
  - De Novo: Technology has no predicate; applicant may need to furnish clinical data showing that the benefits of the technology outweigh the risks

Note: FDA (Food and Drug Administration), SaaS (software as a service), PDT (prescription digital therapeutic).

Medical software payment



- Typically, a technology company enters into an agreement with a doctor to supply the technology for a fee
  - Subscription
  - Per click
- The doctor bills the insurer for furnishing the service that includes the technology

Source: MedPAC interviews with medical technology companies, 2025.

Medicare has covered and paid for SaaS since 2018

- SaaS meets statutory requirements for Medicare coverage and payment if it:
  - Is approved or cleared by the FDA*
  - Fits into a Medicare benefit category and is not explicitly excluded by law
  - Meets other statutory requirements including being reasonable and necessary for the treatment of an illness or injury (improved outcomes or cost effectiveness not required)
  - SaaS items are covered and paid under OPPS, PFS, and IPPS

Note: SaaS (software as a service), FDA (Food and Drug Administration), OPPS (outpatient prospective payment system), PFS (physician fee schedule), IPPS (inpatient prospective payment systems).
* In most cases, an FDA-regulated product must receive marketing authorization for at least one indication to be eligible for consideration of Medicare coverage.

Most PDTs do not meet the statutory requirements for Medicare coverage and payment

- Payment for PDTs for mental health treatment under the PFS began in January 2025
- Most other PDTs are not consistent with Medicare's definition of DME and do not fit into other benefit categories

Note: PDT (prescription digital therapeutic), PFS (physician fee schedule), DME (durable medical equipment).

Medical software technologies are covered and paid under several FFS Medicare payment systems

- OPPS: Separate payments for SaaS items in 19 HCPCS codes
- PFS: Payment for the same SaaS items as the OPPS; also has payment for a PDT for digital mental health therapy
- IPPS: Different SaaS items from OPPS and PFS; SaaS items are generally packaged into MS–DRGs
- DME fee schedule: Some coverage and payment for PDT items, but most PDTs do not meet DME requirements

Note: FFS (fee-for-service), OPPS (outpatient prospective payment system), SaaS (software as a service), HCPCS (Healthcare Common Procedure Coding System), PFS (physician fee schedule), PDT (prescription digital therapeutic), IPPS (inpatient prospective payment systems), MS–DRG (Medicare severity diagnosis related group), DME (durable medical equipment).

FFS use of and payment for SaaS under the OPPS

- Most of the 19 HCPCS codes for SaaS items provide enhancements of imaging scans (augmentative):
  - E.g., estimated fractional flow reserve from CTA (FFRCT) image for patients with symptoms of coronary artery disease
- For most SaaS items, FFS use in HOPDs was low in 2023:
  - Exception: FFRCT
    - 14,000 uses
    - $12.7 million in OPPS payments
  - No other HCPCS code had more than 570 uses or more than $0.3 million in OPPS payments

Note: FFS (fee-for-service), SaaS (software as a service), OPPS (outpatient prospective payment system), HCPCS (Healthcare Common Procedure Coding System), CTA (computed tomography angiography), HOPD (hospital outpatient department).
Source: MedPAC analysis of Medicare outpatient claims, 2023.

FFS use of and payment for SaaS under the PFS

- Low use of and payments for SaaS items in 2023
  - No HCPCS code had more than 3,600 uses or more than $0.2 million in PFS payments
- Most SaaS items are carrier priced because CMS has had difficulty setting the practice expense portion of PFS payments:
  - Under carrier pricing, payment is set by Medicare administrative contractors, usually case by case
  - This contrasts with national payment rates set by CMS for most services

Note: FFS (fee-for-service), SaaS (software as a service), PFS (physician fee schedule), HCPCS (Healthcare Common Procedure Coding System).
Source: MedPAC analysis of Medicare carrier claims, 2023.

FFS use of and payment for SaaS under the IPPS

- Technology like SaaS is usually bundled into the payment rate for the applicable MS–DRG
- Manufacturers can apply for a new-technology add-on payment (NTAP), which provides payments in addition to the MS–DRG payment for 2–3 years
- In 2025, 4 SaaS items have NTAP status
- In 2023, 1 SaaS item had NTAP status:
  - 3,200 uses
  - $3.2 million in NTAP payments

Note: FFS (fee-for-service), SaaS (software as a service), IPPS (inpatient prospective payment systems), MS–DRG (Medicare severity diagnosis related group).
Source: MedPAC analysis of Medicare inpatient claims, 2023.

Coverage and payment for PDTs under the DME fee schedule

- Medicare covers and pays for DME (medical equipment prescribed by a clinician and needed at a patient's home) if it meets 5 criteria:
  - Can withstand repeated use
  - Has an expected life of at least 3 years
  - Is primarily and customarily used to serve a medical purpose
  - Is not generally useful to an individual in the absence of an illness or injury
  - Is appropriate for use in the home
- Most PDTs do not meet the criteria for DME coverage and payment
  - Usually used solely on a personal device (phone, tablet, smartwatch), which is not primarily used to serve a medical purpose

Note: PDT (prescription digital therapeutic), DME (durable medical equipment).

Interviews with stakeholders

Interviews with stakeholders

- To gain a better understanding of the challenges facing stakeholders, we reached out to many insurers and developers to request interviews
- Ultimately, we were able to interview:
  - 2 developers that produce augmentative SaaS items
  - 2 developers of automated software that diagnoses conditions
  - 1 commercial insurer

Note: SaaS (software as a service).

Interview findings: Developer perspective

Theme: FDA approval or clearance time frame

- Developers that were first to apply for FDA approval or clearance said they waited longer for a decision than those that were able to use an existing item as a predicate
- Developers mentioned time and cost of approval/clearance as a challenge for start-ups
- Developers noted that additional approvals were sometimes needed in unanticipated circumstances, such as changes to software interfaces or algorithms

Note: FDA (Food and Drug Administration).
Source: MedPAC interviews with medical technology companies, 2025.

Theme: Insurance coverage

- Developers reported that once FFS Medicare and Medicare Advantage covers and pays for an item, other insurers often follow
- However, developers noted they often had to work with individual states to obtain Medicaid coverage and individual insurers to obtain coverage by commercial plans
- One developer said it was difficult to get insurers to understand the value of their technology in coverage and payment conversations with insurers

Note: FFS (fee-for-service).
Source: MedPAC interviews with medical technology companies, 2025.

Theme: Billing and payment

- To bill an insurer for a technology, a billing code is needed
- If an existing code was not available to bill insurers for the new technology, developers noted that creating a new code took longer than anticipated
- Most developers we interviewed expressed unhappiness with the payment amounts established by insurers, including Medicare and Medicaid, saying that the payment amounts are too low

Source: MedPAC interviews with medical technology companies, 2025.

Interview findings: Insurer perspective

Theme: Need for effectiveness data

- This insurer requires technology companies to show the net benefits to patients (not typically required for FDA approval or clearance)
- The insurer explained that many new technologies show promise but lack robust evidence as to:
  - Whether outcomes are the same or better as those of existing technology or treatments
  - Known side effects and whether they are less bothersome than those of existing technology or treatments
- The insurer said technologies are often created by companies who lack clinical staff, and they may not be familiar with insurers' requirements for rigorous effectiveness data

Note: FDA (Food and Drug Administration).
Source: MedPAC interview with an insurer, 2025.

Discussion

- Questions
- Feedback on materials
- Continue to monitor coverage, use, and spending for medical software technologies
- Commissioner ideas for future analytic work

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