Medicare coverage of and payment for software as a medical service: An overview

Nancy Ray, Dan Zabinski, and Corinna Cline

November 2, 2023
Presentation roadmap

1. Definition and characteristics of SaaS and PDTs
2. Statutory requirements for Medicare coverage
3. Payment for software as a medical service in Medicare’s payment systems
4. Principles for payment in FFS Medicare
5. Discussion

Note: SaaS (software as a service), PDT (prescription digital therapeutic), FFS (fee-for-service).
Software as a medical service

• SaaS: Algorithm-driven software that assists clinicians in making clinical assessments
  • e.g., AI-driven software that analyzes images of the eye taken by a retinal camera to diagnose diabetic retinopathy
• PDTs: Software applications delivered on beneficiaries’ personal devices that treat an illness or injury
  • e.g., cognitive behavioral therapy to treat insomnia

Note: AI (artificial intelligence), FDA (Food and Drug Administration), PDT (prescription digital therapeutic), SaaS (software as a service).
Characteristics of SaaS and PDTs

• Software that is used or prescribed by clinicians for one or more medical purposes without being part of a hardware medical device
  • The FDA refers to such medical software as Software as a Medical Device (SaMD)

• The FDA approves (clears) most SaaS and PDTs:
  • As Class II devices (moderate to high risk)
  • Under the 510(k) or De Novo device approval pathways

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

- Item or service (including SaaS and PDTs):
  - Is approved or cleared by the FDA*
  - Fits into a covered Medicare benefit category
  - Meets other statutory requirements including being reasonable and necessary for the treatment of an illness or injury
- Since 2018, Medicare has covered and paid for SaaS
- Medicare does not cover most PDTs because:
  - Such software does not fit into an existing Medicare benefit category
  - Such software is not consistent with Medicare’s definition of durable medical equipment

*In most cases, an FDA-regulated product (e.g., prescription drugs and devices) must receive marketing authorization for at least one indication to be eligible for consider for Medicare coverage.

**Note:** FDA (Food and Drug Administration), SaaS (software as a service), PDT (prescription digital therapeutic).
Software as a medical service in the hospital outpatient prospective payment system (OPPS)

- SaMS in the form of SaaS is covered under the OPPS
- OPPS covered service: Falls in a Medicare benefit category, has a HCPCS (billing) code, safe to provide in HOPD setting
- Under the OPPS, CMS determines whether a covered service is separately payable or packaged
  - Separately payable: Relatively costly or reason for visit
  - Packaged: Adjunctive to or supportive of a separately payable service

Note: SaMS (software as a medical service), SaaS (software as a service), OPPS (outpatient prospective payment system), HCPCS (Healthcare Common Procedure Coding System), HOPD (hospital outpatient department).
Payment status of SaaS in the OPPS

- OPPS has 10 HCPCS codes for covered SaaS
  - Example: HeartFlow analyzes data from CT scans for patients with symptoms of coronary artery disease
- The covered SaaS devices have some attributes that suggest they should be packaged and other attributes that suggest they should be separately payable
- CMS: Generally chose separately payable status for SaaS
  - In 2022, 3 of 10 covered SaaS devices were packaged; remaining 7 SaaS devices were separately payable
  - In 2023, all 10 SaaS devices are separately payable (never packaged)

Note: SaaS (software as a service), OPPS (outpatient prospective payment system), HCPCS (Healthcare Common Procedure Coding System), CT (computed tomography).
As of 2022, volume and spending on SaaS have been low in OPPS

- In 2022, of the 7 separately payable SaaS devices, only one, HeartFlow, had appreciable volume (8,665 uses) and spending ($8.4 million)
- LiverMultiScan and Cleerly Labs had volume of less than 100 uses and spending of less than $50,000
- The other separately payable SaaS devices had no volume or spending

**Note:** SaaS (software as a service), OPPS (outpatient prospective payment system).
Payment for SaMS in the Medicare physician fee schedule

• The 10 SaaS devices covered under the OPPS are also covered under the Medicare physician fee schedule (PFS)
• PFS has less packaging than the OPPS; all 10 SaaS devices have always been separately payable under PFS
• CMS has had difficulty setting the practice expense portion of the PFS payment rates for most of these SaaS devices
• Therefore, 2023 PFS payments for eight of these SaaS devices are set by Medicare’s administrative contractors (rather than by CMS), generally on a case-by-case basis

Note: SaMS (software as a medical service), SaaS (software as a service), OPPS (outpatient prospective payment system).
Payment for SaMS in the inpatient prospective payment systems

• Under inpatient prospective payment systems (IPPS), technology like SaMS is usually bundled into the payment rate for the applicable MS-DRG

• Manufacturers of new technology can apply for a new-technology add-on payment (NTAP), which provides payments in addition to the MS-DRG payment for two to three years

Note: SaMS (software as a medical service), MS-DRG (Medicare severity-diagnosis related group).
Criteria for NTAP status

- Usually, a new technology must meet three criteria for NTAP status:
  - Not substantially similar to existing technology (new)
  - High cost in relation to the payment rate of the applicable MS-DRG
  - Represents substantial clinical improvement

- However, if the FDA designates the technology as Breakthrough, the new technology must meet only the cost criterion for NTAP status

- Six SaMS devices have received NTAP status
  - Two SaMS devices, ContaCT and Caption Guidance, no longer have NTAP status
  - Four SaMS devices began NTAP status in fiscal year 2024; all have Breakthrough status

Note: NTAP (new technology add-on payment), MS-DRG (Medicare severity-diagnosis related group), SaMS (software as a medical service), FDA (Food and Drug Administration). A device is granted Breakthrough status if the FDA determines that the device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions and meets at least one of the following: represents breakthrough technology; no approved or cleared alternatives exist; offers significant advantages over existing approved or cleared alternatives; or device availability is in the best interest of patients.
Payment for SaMS in the durable medical equipment (DME) fee schedule

• DME: Medical equipment prescribed by a clinician, that meet five criteria, and are needed at a patient’s home
• PDTs are the type of SaMS applicable to the DME system
• Medicare covers software embedded in a device if it meets the DME criteria; for example:
  • Covered: Software and devices used together to generate speech for those with severe impediments
  • Covered: PDTs in which the software and medical device are integral to each other
  • Not covered: PDTs in which software is solely usable on personal devices

Note: SaMS (software as a medical service), PDT (prescription digital therapeutics).
Discussion
Principles for payment in FFS Medicare

• Ensure beneficiary access to high-quality services
• Utilize payment approaches that:
  • Promote provider efficiency and delivery of high-quality care
  • Spur price competition among manufacturers of similar products
  • Create incentives for the development of software that leads to substantial clinical improvement with an appropriate reward for innovation and affordability for beneficiaries and taxpayers

Note: FFS (fee-for-service).
Discussion: How should Medicare ensure that covered services improve beneficiaries’ health outcomes?

• Some devices that pose low- to moderate-risk rely on evidence showing that they are substantially equivalent to existing devices for FDA market authorization.

• Medicare could require that a manufacturer of a SaaS/PDT provide evidence that its product results in a clinically meaningful improvement for Medicare beneficiaries compared with the standard of care.

• Alternatively, a coverage with evidence development policy could be used for new software that lacks evidence showing it has a positive effect for Medicare beneficiaries.

Note: FDA (Food and Drug Administration), SaaS (software as a service), PDT (prescription digital therapeutic).
Discussion: How should Medicare generally pay for covered SaMS that is separate from the device?

- MedPAC 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.
- Paying separately for items and services (including medical software):
  - 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)
  - Shifts financial pressure from providers to Medicare

Note: SaMS (software as a medical service).
Discussion: How should Medicare set the payment rate for items and services paid for under fee schedules?

• Bundles/packaging generally not used under the fee schedules for clinician services and durable medical equipment

• Options for setting a payment rate:
  • The manufacturer’s list price
  • A market-based price determined by the manufacturer’s pricing decisions, which may not be related to the clinical value of the product
  • A new product’s net clinical benefit compared with the standard of care
  • Accounting for efficiencies from the new technology when determining Medicare’s payment rate
Discussion questions

• How should Medicare ensure that covered services improve beneficiaries’ health outcomes?
• How should Medicare generally pay for covered medical software that is separate from the device?
• How should Medicare set the payment rate for items and services paid for under fee schedules?
• Questions about the material?
Medicare Payment Advisory Commission

meetingcomments@medpac.gov
www.medpac.gov
@medicarepayment