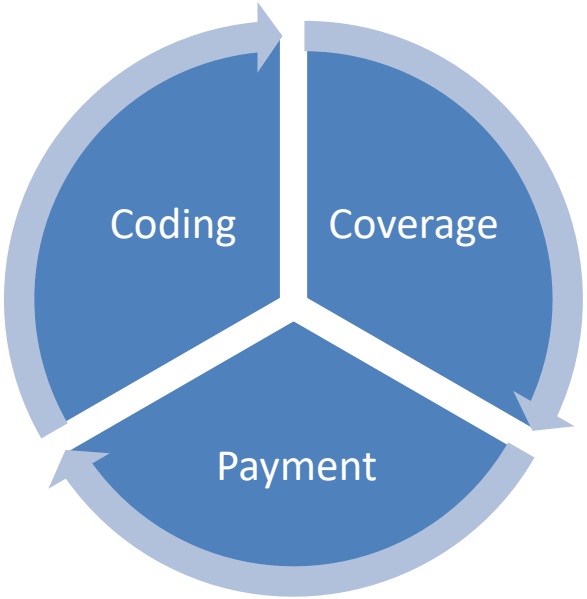
Coverage, Coding and Payment – Collaboration Between FDA and CMS

Cybil Roehrenbeck, JD

FDLI

Coding, Coverage & Payment



Coding

Health Care Activity/Item	Adopted Code Set
Diagnoses (ICD-10-CM) Procedures (ICD-10-PCS)	ICD-10 – International Classification of Diseases, 10th edition
Outpatient services/procedures	CPT – Current Procedure Terminology
Health care equipment and supplies Services not covered by CPT codes	Health Care Common Procedure Coding System (HCPCS)
Dental procedures	CDT – Code on Dental Procedures and Nomenclature
Drug products	NDC – National Drug Codes

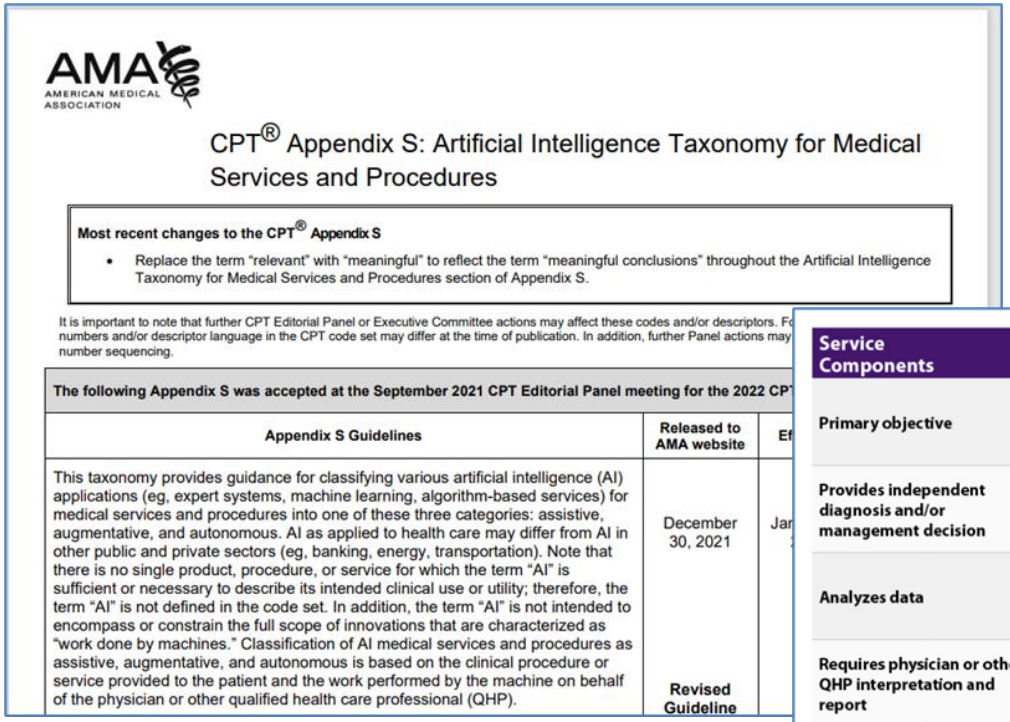
Coding

- The CPT Editorial Panel considers applications for new codes and revisions to existing codes.
- The Panel's deliberations include hearing from specialty societies, clinicians, and other interested parties.
- The CPT Editorial Panel meets during a regular annual schedule to review and approve codes.
- Special workgroups for areas of emerging medical services or technologies (for example, digital health or genomics) meet to discuss issues of interest and novel coding methodologies.
- https://www.ama-assn.org/about/cpt-editorial-panel

Coding

- Category I codes
- Category III codes
- AMA CPT Digital Medicine Payment Advisory Group (DMPAG)
- Artificial Intelligence (AI) working group

Coding



AMA
AMERICAN MEDICAL ASSOCIATION

CPT® Appendix S: Artificial Intelligence Taxonomy for Medical Services and Procedures

Most recent changes to the CPT® Appendix S

- Replace the term "relevant" with "meaningful" to reflect the term "meaningful conclusions" throughout the Artificial Intelligence Taxonomy for Medical Services and Procedures section of Appendix S.

It is important to note that further CPT Editorial Panel or Executive Committee actions may affect these codes and/or descriptors. Fo
numbers and/or descriptor language in the CPT code set may differ at the time of publication. In addition, further Panel actions may
number sequencing.

The following Appendix S was accepted at the September 2021 CPT Editorial Panel meeting for the 2022 CP

Appendix S Guidelines	Released to AMA website	Ef
This taxonomy provides guidance for classifying various artificial intelligence (AI) applications (eg, expert systems, machine learning, algorithm-based services) for medical services and procedures into one of these three categories: assistive, augmentative, and autonomous. AI as applied to health care may differ from AI in other public and private sectors (eg, banking, energy, transportation). Note that there is no single product, procedure, or service for which the term "AI" is sufficient or necessary to describe its intended clinical use or utility; therefore, the term "AI" is not defined in the code set. In addition, the term "AI" is not intended to encompass or constrain the full scope of innovations that are characterized as "work done by machines." Classification of AI medical services and procedures as assistive, augmentative, and autonomous is based on the clinical procedure or service provided to the patient and the work performed by the machine on behalf of the physician or other qualified health care professional (QHP).	December 30, 2021 Revised Guideline	Jar

Service Components	AI Category: Assistive	AI Category: Augmentative	AI Category: Autonomous
Primary objective	Detects clinically relevant data	Analyzes and/or quantifies data in a clinically meaningful way	Interprets data and independently generates clinically meaningful conclusions
Provides independent diagnosis and/or management decision	No	No	Yes
Analyzes data	No	Yes	Yes
Requires physician or other QHP interpretation and report	Yes	Yes	No
Examples in CPT code set	Computer-aided detection (CAD) imaging (77048, 77049, 77065-77067, 0042T, 0174T, 0175T)	Continuous glucose monitoring (CGM) (95251), external processing of imaging data sets	Retinal imaging (92229)

Payment

- Once a *new* code is approved, the Centers for Medicare & Medicare Services, and other payors, *may* consider whether to reimburse for that service / code.
- Medicare reimbursement is proposed via an annual rulemaking cycle. A physician office code, for example, would be part of CMS' annual Medicare Physician Fee Schedule Rulemaking.
- CMS staff and leadership deliberate considering whether reimbursement for a particular code meets Medicare statutory and regulatory requirements.
- Payment is not automatic just because you have a code.
- The AMA Relative Value Update Committee (RUC) provides recommendations to CMS regarding the valuation of services / codes using specialty society and other stakeholder input and data.

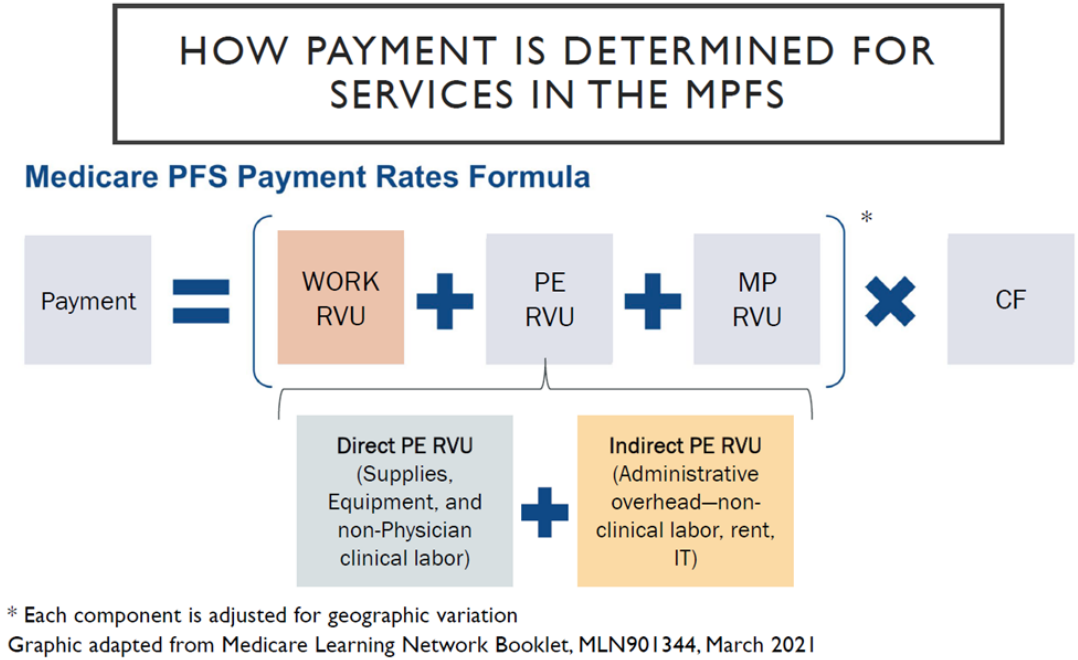
Payment

- Annual Medicare Payment Rules:
  - Medicare Physician Fee Schedule
    - Also includes nursing and other advanced practice practitioners
  - Outpatient Prospective Payment System
    - Also includes ASCs
  - Inpatient Prospective Payment System
  - Home Health
    - Also includes home infusion
  - Durable Medical Equipment (DME)
- One bite at the apple per year!
- Medicare payment sets the tone for commercial payers.

Payment

- Statutory payment methodologies
- Medicare physician payment Relative Value Units (RVUs):
  - Physician Work RVU
    - Time, technical skill & effort, judgment
  - Practice Expense RVU
    - Non-physician clinician and non-clinican labor, expenses for building space equipment and office supplies
    - Direct vs. indirect
  - Malpractice RVU
    - Malpractice insurance cost

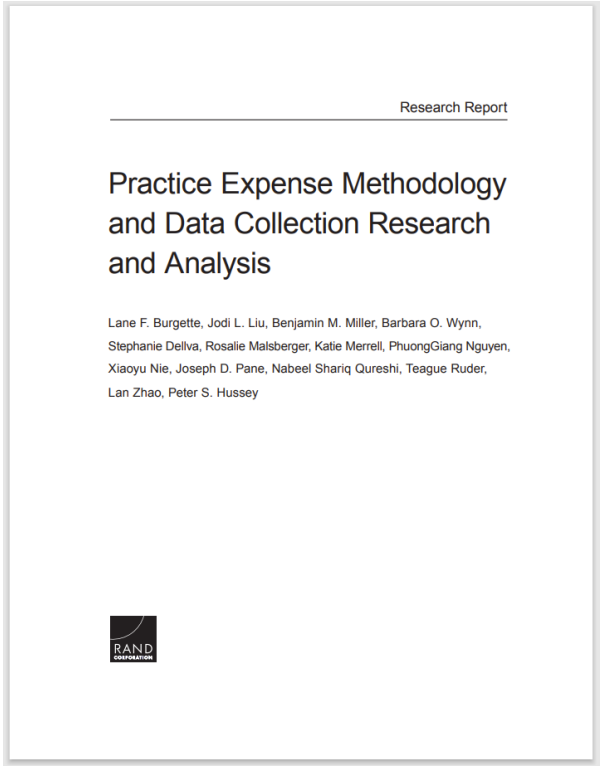
Payment



* Each component is adjusted for geographic variation

Graphic adapted from Medicare Learning Network Booklet, MLN901344, March 2021

Payment



Research Report

Practice Expense Methodology and Data Collection Research and Analysis

Lane F. Burgette, Jodi L. Liu, Benjamin M. Miller, Barbara O. Wynn, Stephanie Dellva, Rosalie Malsberger, Katie Merrell, PhuongGiang Nguyen, Xiaoyu Nie, Joseph D. Pane, Nabeel Shariq Qureshi, Teague Ruder, Lan Zhao, Peter S. Hussey

RAND CORPORATION

EXAMPLE: "PER CLICK" FEES

- Artificial Intelligence (AI) tools are starting to be used in clinical settings, e.g., to interpret images from eye exams
- When practices pay for these tools on a per-use basis, there are questions as to whether the payment should be paid as a direct or indirect expense
  - AI tools are not accounted for in current data
  - Practices may incur an expense that is directly tied to a specific patient encounter
  - Little additional indirect PE may be incurred for such services
- Transitioning away from rigid indirect/direct pools could provide flexibility for new expense types such as AI tools

Payment

- Certain services may qualify for payment as a New Technology Ambulatory Payment Classification (APC) under the Outpatient Prospective Payment System (OPPS).
- To be eligible, the service:
  - Could not have been adequately represented in the claims data being used for the most current annual OPPS payment update.
  - Does not qualify for an additional payment under the transitional pass-through provisions
  - Cannot reasonably be placed in an existing clinical APC group
  - Falls within the scope of Medicare benefits
  - Reasonable and necessary
- New Technology APCs may be assigned for 2-3 years (or longer)
- Applications occur quarterly (first business day of March, June, September, December)

Payment

- Certain new medical services and technologies may be eligible for a New Technology Add-on Payment (NTAP) under the Inpatient Prospective Payment System (IPPS) per 42 CFR § 412.87(b).
- To qualify for an NTAP payment, three criteria must be met:
  - the medical service or technology must be **new**;
  - the medical service or technology must be **costly** such that the MS-DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; *and*
  - medical service or technology must demonstrate a **substantial clinical improvement** over existing services or technologies.
- Payments are limited to the lesser of 65% of the costs of the technology, or 65% of the amount by which the costs of the case exceed the standard MS–DRG payment
- Certain new medical services and technologies may be eligible to apply for NTAP under an alternative pathway. For example, technologies that are part of FDA's Breakthrough Devices Program may qualify.

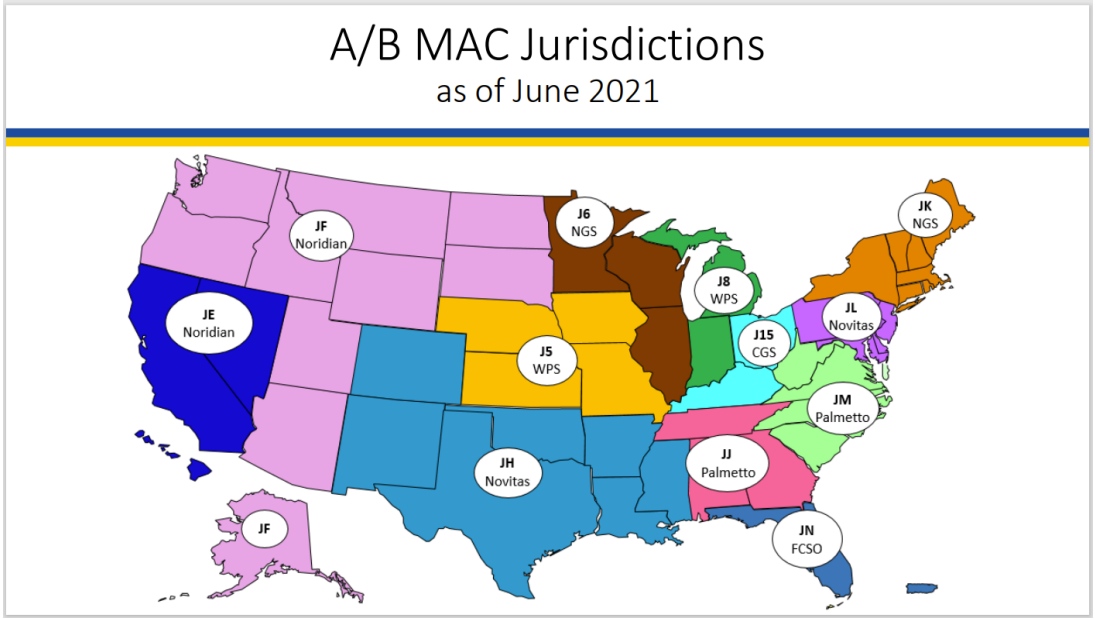
Payment

- What are the criteria that a device must meet to be eligible for a **transitional pass-through payment**?
- If required by the FDA, the device must have received FDA approval or clearance.
  - This requirement is met if a device has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with §§405.203 through 405.207 and 405.211 through 405.215 of Title 42 of the Code of Federal Regulations or has received another appropriate FDA exemption.
- 2. The device must —
  - a. Be an integral part of the service furnished;
  - b. Be used for one patient only;
  - c. Come in contact with human tissue; and
  - d. Be surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion.
- 3. The device is not any of the following:
  - a. Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1).
  - b. A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than radiological site marker).

Payment

- Other considerations:
  - Value based payment models
  - Quality metrics (for example, HEDIS)
  - Pairing with existing services and codes (for example, Evaluation and Management E/M codes)
  - Global billing
  - Supervision requirements
  - Geographic adjustments

Coverage



- National Coverage Determinations (NCDs) vs. Local Coverage Determinations (LCDs)

Coverage

- When and how to engage with CMS regarding a coverage determination is a matter of strategy:
  - Does a negative coverage decision exist?
  - What evidence will be required (and how might that differ from FDA's required clinical evidence)?
  - What will utilization be in the first year of billing?
  - Which MAC is best to engage with first?
  - How to interface with national CMS coverage staff regarding LCD issues?

Coverage

- CMS' Medicare Coverage of Innovative Technologies
  - Would have provided an automatic, immediate 4 year coverage period for FDA-approved "breakthrough technologies"
  - Coined the "MCIT Pathway" for national coverage
  - Trying to address issue of 9 – 12 months for new coverage policies (conservative estimate)

Coverage

Viewpoint | Health Care Policy and Law

ONLINE FIRST FREE

October 12, 2022

A Vision of Medicare Coverage for New and Emerging Technologies—A Consistent Process to Foster Innovation and Promote Value

Lee A. Fleisher, MD[1]; Jonathan D. Blum, MPP[2]

» Author Affiliations | Article Information

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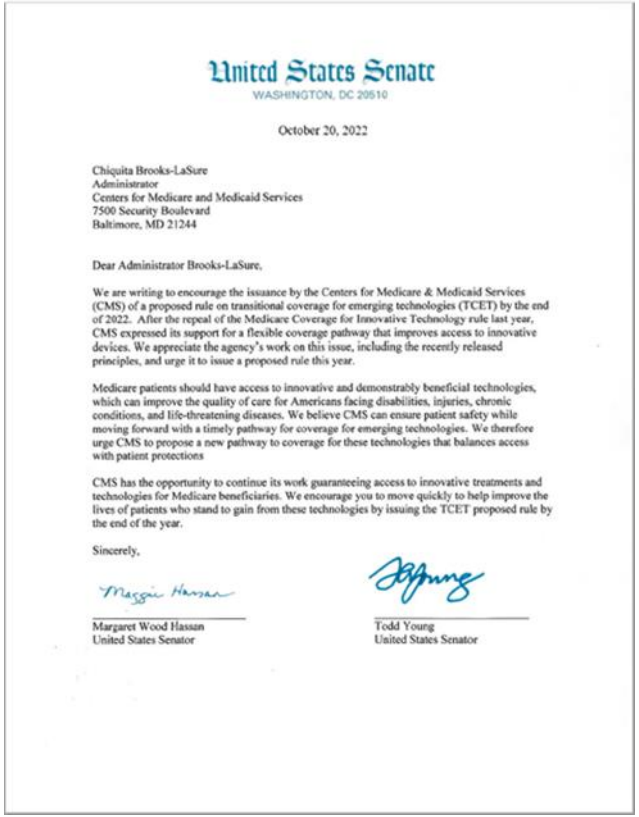
Therapeutic advances enable new treatments and cures for disease. The Centers for Medicare & Medicaid Services (CMS) is committed to ensuring access to emerging technologies that benefit Medicare beneficiaries. For individuals covered by Medicare Part A or Part B, Congress has charged CMS with determining whether items and services are reasonable and necessary to diagnose or treat an illness or injury, or "to improve the functioning of a malformed body member."[1] The US Food and Drug Administration (FDA) determines that the item or service (eg, drug, biologic, medical device) is safe and effective for the intended population.

Coverage

- Bipartisan Senate letter on temporary transitional coverage for emerging technologies (TCET).
- Led by Senators Maggie Hassan (D-NH) and Todd Young (R-IN).
- Follow up to pull back of the Medicare Coverage of Innovative Technologies (MCIT) regulation.
- 16 co-signors
- Senators ask CMS to issue a proposed rule by year's end on coverage for innovative tech.



United States Senate
WASHINGTON, DC 20510

October 20, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure,

We are writing to encourage the issuance by the Centers for Medicare & Medicaid Services (CMS) of a proposed rule on transitional coverage for emerging technologies (TCET) by the end of 2022. After the repeal of the Medicare Coverage for Innovative Technology rule last year, CMS expressed its support for a flexible coverage pathway that improves access to innovative devices. We appreciate the agency's work on this issue, including the recently released principles, and urge it to issue a proposed rule this year.

Medicare patients should have access to innovative and demonstrably beneficial technologies, which can improve the quality of care for Americans facing disabilities, injuries, chronic conditions, and life-threatening diseases. We believe CMS can ensure patient safety while moving forward with a timely pathway for coverage for emerging technologies. We therefore urge CMS to propose a new pathway to coverage for these technologies that balances access with patient protections

CMS has the opportunity to continue its work guaranteeing access to innovative treatments and technologies for Medicare beneficiaries. We encourage you to move quickly to help improve the lives of patients who stand to gain from these technologies by issuing the TCET proposed rule by the end of the year.

Sincerely,

Margaret Wood Hassan
United States Senator

Todd Young
United States Senator

Questions?

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