MEDICARE BASICS

Payment & Health Care Delivery Policy

Kirsten Tullia, J.D., M.P.H.
Vice President
and Acting Department Head

Richard Price
Senior Vice President
and Head of Research Policy

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MEDICARE OVERVIEW

- Established in 1965 – Title XVIII of the SSA
- Federal health insurance program for three groups of people:
  - Over 65
  - Under 65 with certain disabilities
  - Any age with End-Stage Renal Disease (ESRD)
- The Centers for Medicare & Medicaid Services (CMS) is the federal agency that runs Medicare

FOUR PARTS OF MEDICARE

Part A

Hospital Insurance

Part B

Medical Insurance

Original Medicare

Part C

Medicare Advantage

Part D

Medicare Prescription Drug Coverage

MEDICARE PART A

- **Part A covers:**
  - **Inpatient hospital services**
  - **Skilled nursing facility care**
  - **Some home health care**
  - **Hospice care**
- **Cost:**
  - **Most beneficiaries receive Part A premium free**
  - **Other cost sharing depends on setting of care and length of stay**

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MEDICARE PART A COST SHARING

Inpatient Hospital (2023)

- **Deductible** — $1,600 per benefit period
- **Days 1-60** — No co-payment
- **Days 61-90** — $400 per day
- **Days 91-150** — $800 per day *For up to 60 lifetime reserve days*
- **After 150 Days** — Beneficiary pays 100%

Skilled Nursing Facility (SNF)

- **Days 1-20** — No co-payment
- **Days 21-100** — $200 per day
- **After 100 Days** — Beneficiary pays 100%

Hospice

No co-payment for hospice care; co-payment of up to $5 per outpatient drug prescription

Home Health

No co-payment

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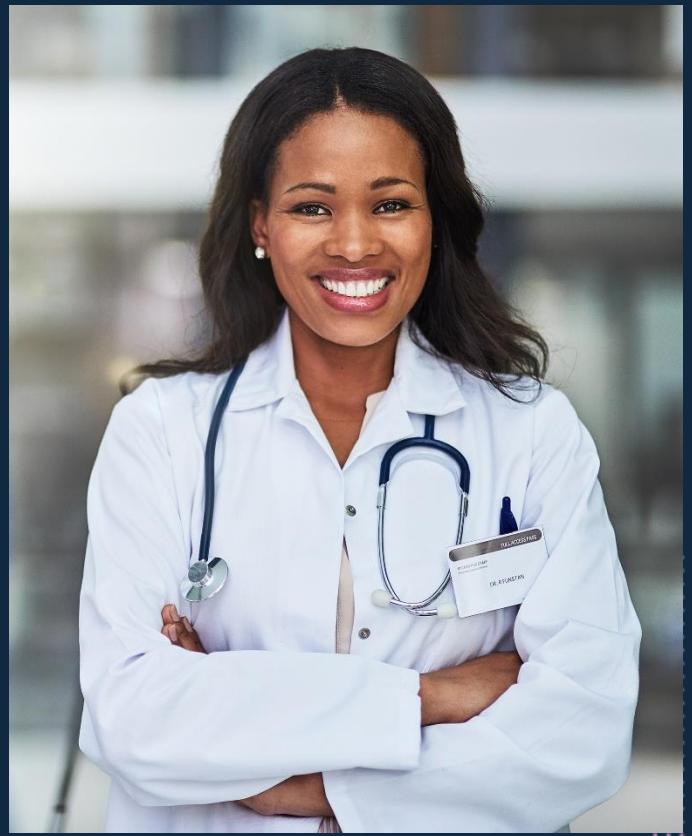
MEDICARE PART B

- **Part B covers:**
  - Physician and other health care provider services
  - Outpatient care
  - Some home health care
  - Durable medical equipment
  - Laboratory tests
  - Many preventive services
- **Cost:**
  - One annual deductible
  - Standard monthly premium with income-related monthly adjustment
  - Coinsurance depends upon service



MEDICARE PART B COST SHARING

- **Physician and Nonphysician Practitioner Services**
  - 20% coinsurance + up to an additional 15% of the amount if the medical provider does not accept assignment
- **Physical, Occupational, and Speech Therapy**
  - 20% coinsurance, certain limits may apply

Outpatient Mental Health Services	20% coinsurance
Outpatient Hospital Care	20% coinsurance
Ambulatory Surgical Services	20% coinsurance
Durable Medical Equipment	20% coinsurance
Clinical Laboratory Tests	No coinsurance or deductible
Home Health	No coinsurance or deductible
Most Preventive Services	No coinsurance

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MEDICARE PART C

Includes all benefits and services covered under Part A and Part B

May include all supplemental benefits and services

Types of MA Plans include:

- Health Maintenance Organizations
- Preferred Provider Organizations
- Private Fee-for-Service Plans
- Special Needs Plans
- Medicare Medical Savings Account Plans

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MEDICARE PART D

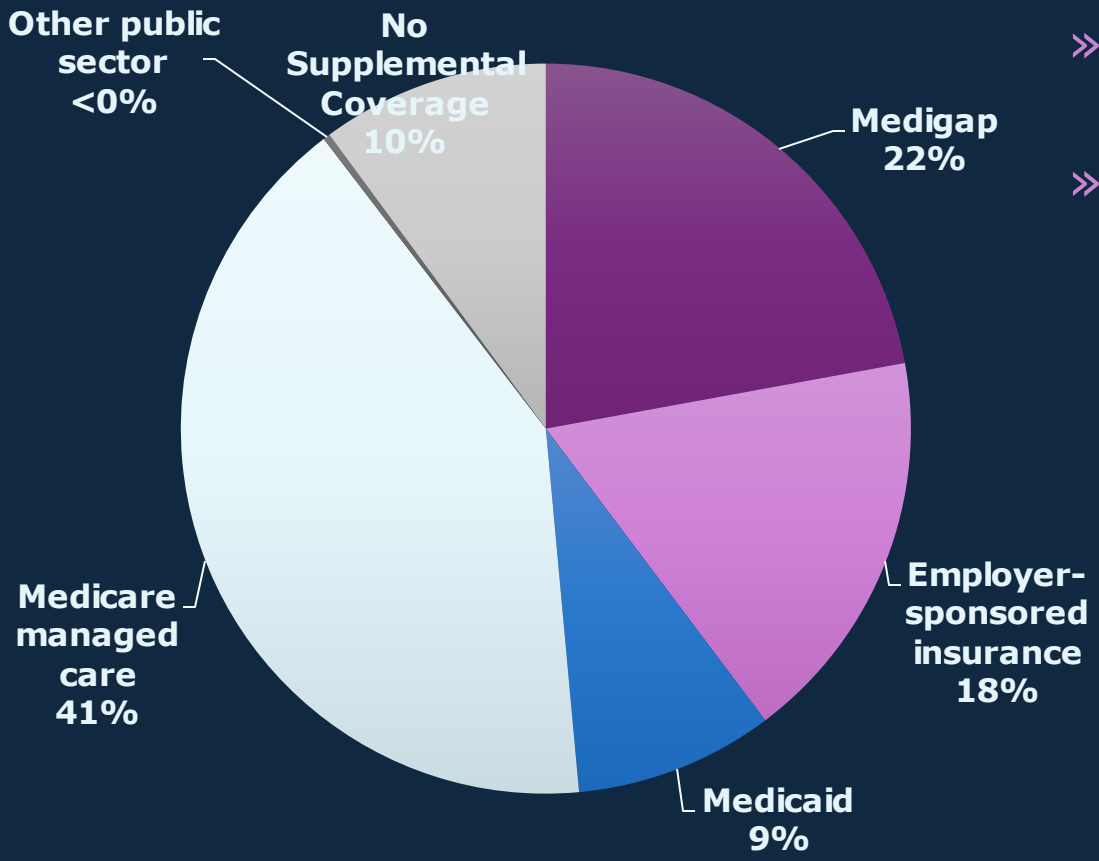
- **Part D covers:**
  - **Prescription drug benefits (outpatient)**
- **Cost:**
  - **Premiums, deductibles, and copayment/coinsurance vary by plan**

MEDICARE OPTIONS

- **Medicare beneficiaries may choose to participate in:**
  - **Original Medicare – Part A and Part B services through original or "traditional" Medicare with optional Part D coverage through a stand-alone Prescription Drug Plan**
  - **Part A and Part B services through an MA Plan, with Part D coverage included in some MA Plans**

- **Note: Some beneficiaries may have a Medicare supplemental plan that fill in the gaps of cost sharing required under the program (employer-based plans and individually purchased Medigap plans)**

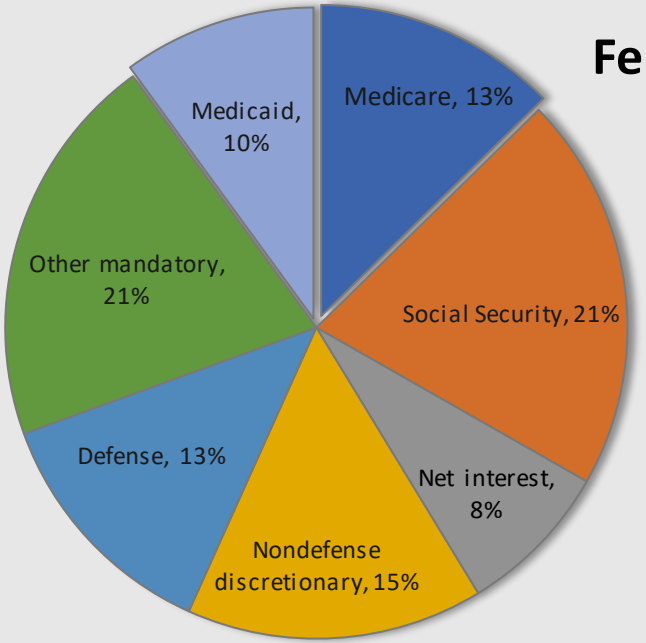
SUPPLEMENTAL COVERAGE



- Medicare doesn't pay *all* health care costs
- Most beneficiaries living in the community have coverage that supplements or replaces the Medicare benefit package

Data from MedPAC 2022 Data Book

Medicare Accounts for 13% of Federal Spending



Federal Spending, 2022

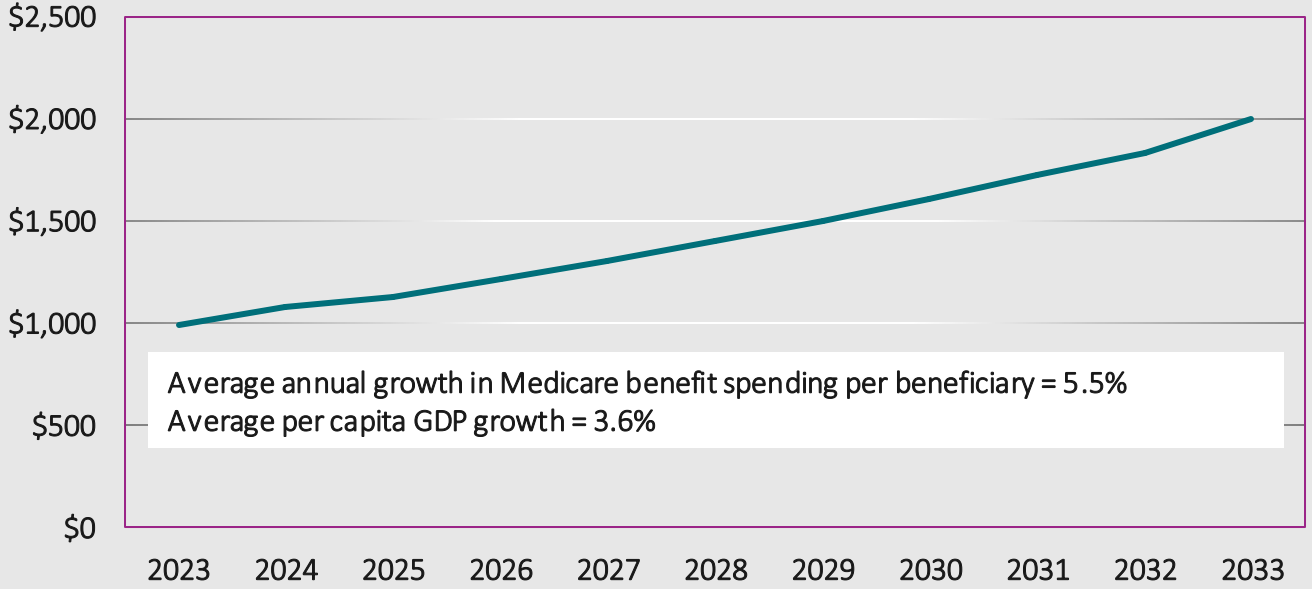
Total = $5.9 trillion

Note: Spending is net of offsetting receipts, such as premiums paid by Medicare beneficiaries. Figure total does not add to 100 percent due to rounding.

Source: Congressional Budget Office. *The Accuracy of CBO's Budget Projections for Fiscal Year 2022,* January 2023.

Medicare Spending Will Double in 10 years

Projected Medicare spending in billions

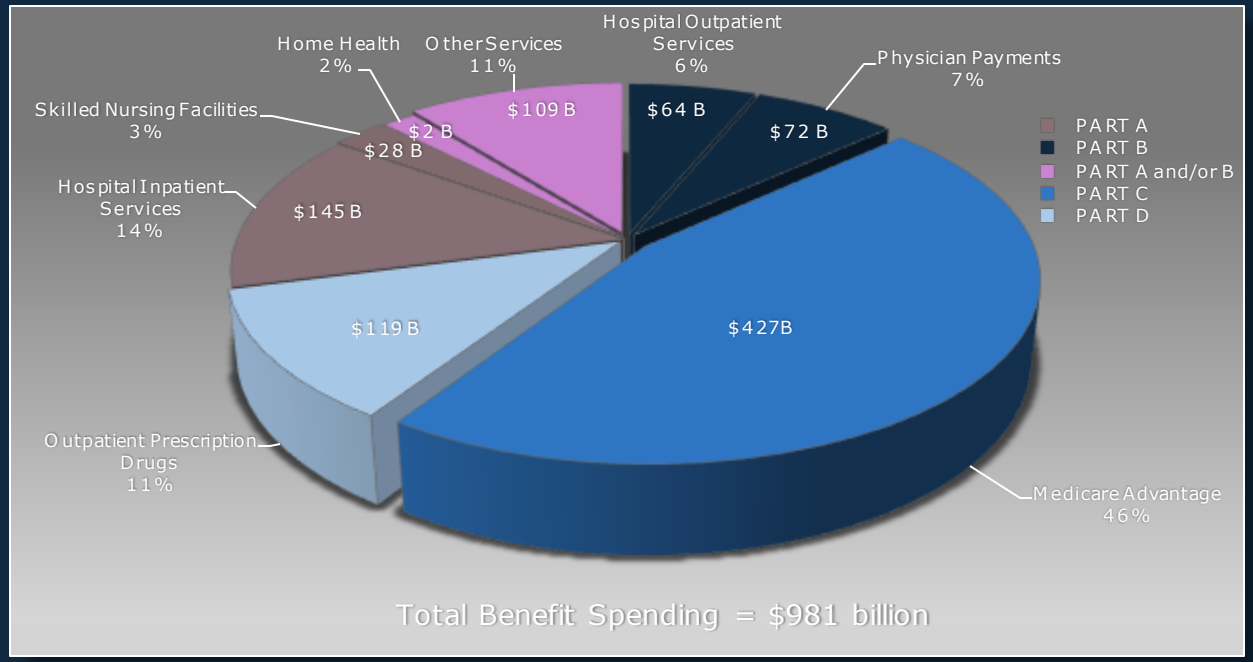


Sources: Congressional Budget Office, The Budget and Economic Outlook, February 2023; and 2023 Medicare Trustees Report

SOME STATS ON SCOPE OF THE PROGRAM

- **In 2020:**
  - **Medicare is the single largest purchaser of personal health care, accounting for 22% of total national spending for personal health care**
  - **65 million beneficiaries enrolled in Medicare**
  - **4,300+ hospitals, 3,000 participating**
  - **14,000 skilled nursing facilities participating**
  - **1.1 million physicians/other HCPs billing Medicare**

Projected Medicare Benefit Spending by Category, FY2022



Source: Congressional Budget Office, "May 2022 Medicare Baseline" .

Note: Dollar amounts in billions. Totals may not add up to 100% due to rounding.

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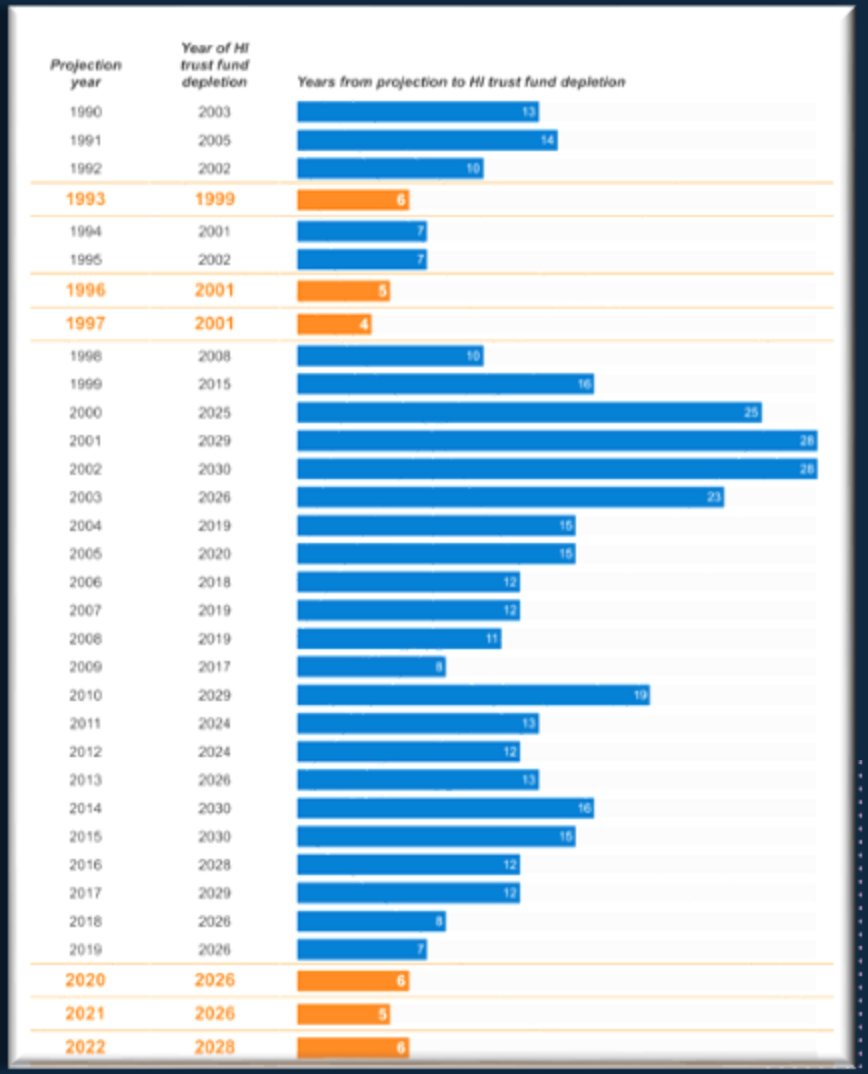
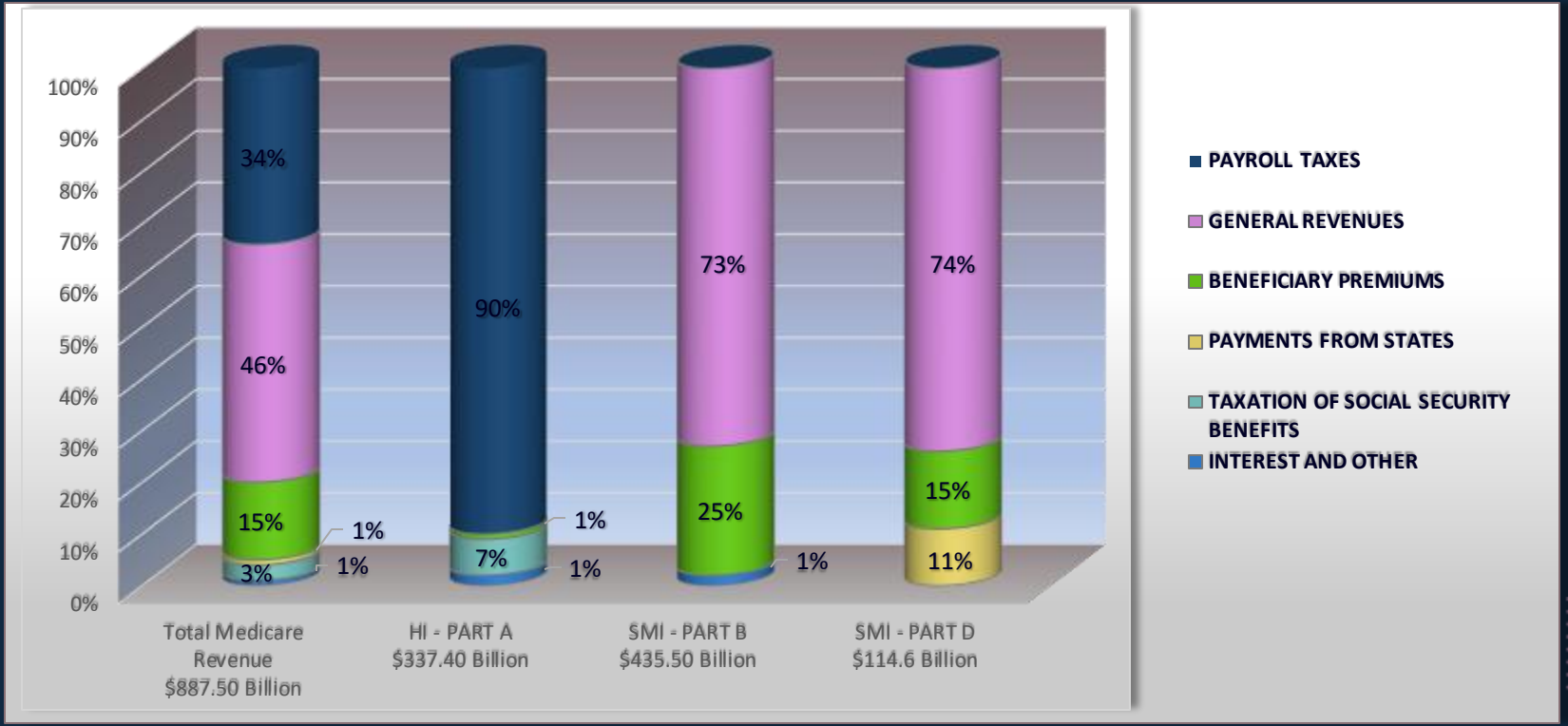
SOLVENCY OF THE MEDICAL HOSPITAL INSURANCE TRUST FUND

- The solvency of the Part A Medicare Hospital Insurance Trust Fund is measured by the level of assets in the Trust Fund.
- In years when annual income from payroll taxes exceeds benefits spending, the asset level increases.
- When annual spending exceeds income, the asset level decreases.

SOURCE: Kaiser Family Foundation analysis of data from the 2022 Medicare Trustees Report.



SOURCES OF MEDICARE REVENUE, CY2021



Source: Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2020 Report of the Medicare Trustees, Table II.B1.

Notes: Totals may not add to 100% due to rounding. HI is the Hospital Insurance Trust Fund, and SMI is the Supplementary Medical Insurance Trust Fund.

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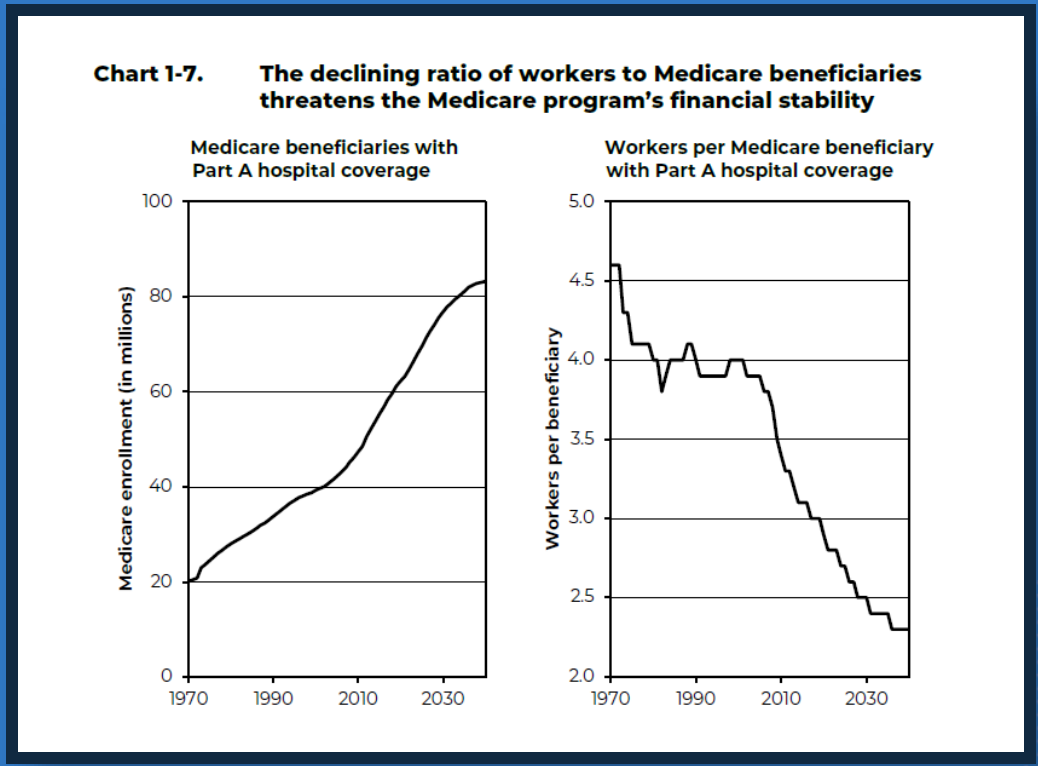
DECLINING RATIO OF WORKERS TO MEDICARE BENEFICIARIES TO FUND PART A BENEFITS

As the baby-boom generation ages, enrollment in the Medicare program is surging. By 2030, all baby boomers will have reached the age of eligibility for the Medicare program, and 77 million beneficiaries are expected to have Medicare Part A Hospital Insurance—up from 62 million beneficiaries in 2020.

While Medicare enrollment is rising, the number of workers per beneficiary is rapidly declining. Part A Hospital Insurance is primarily financed by workers' Medicare payroll taxes. However, the number of workers per Medicare beneficiary with Part A Hospital Insurance has declined from 4.6 in the early years of the program to 2.9 in 2020 and is projected to fall to 2.5 by 2030.



Source: **Health Care Spending and the Medicare Program, MedPAC, July 2022**

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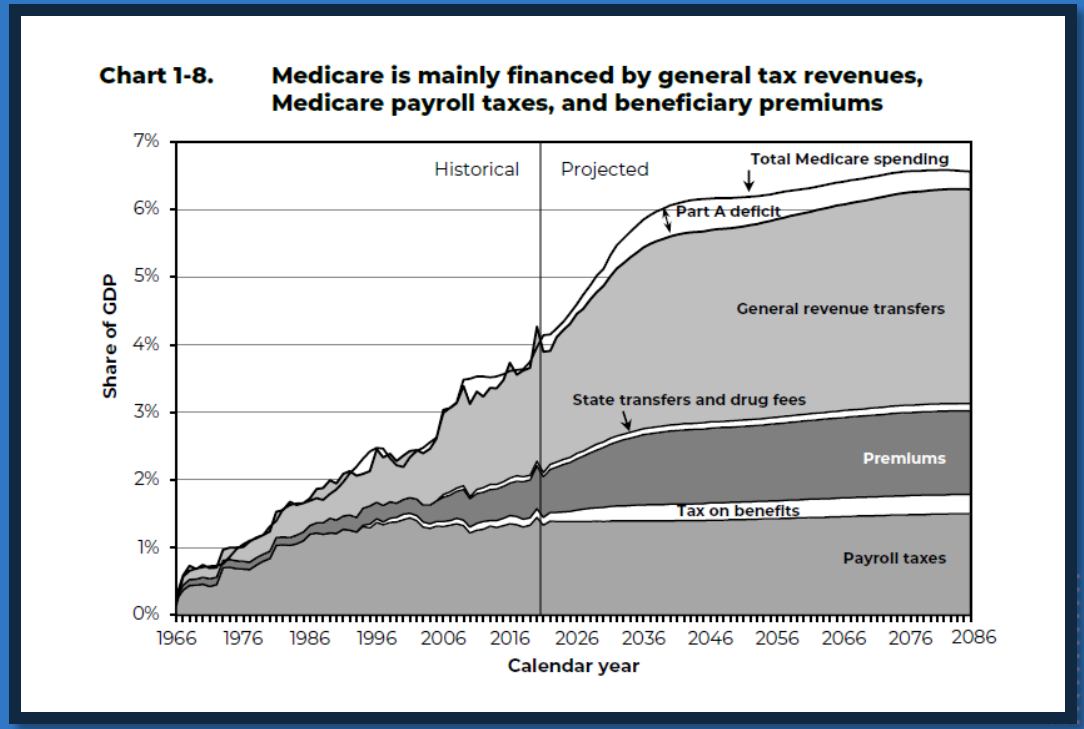
GENERAL REVENUE IS PAYING FOR GROWING SHARE OF MEDICARE SPENDING

Note: GDP (gross domestic product). These projections are based on the Trustees' intermediate set of assumptions and do not reflect the potential effects of the coronavirus pandemic. "Tax on benefits" refers to the portion of income taxes that higher income individuals pay on Social Security benefits, which is designated for Medicare. "State transfers" (often called the Part D "clawback") refers to payments from the states to Medicare for assuming primary responsibility for prescription drug spending that were mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. "Drug fees" refers to the fee imposed by the Affordable Care Act of 2010 on manufacturers and importers of brand-name prescription drugs. These fees are deposited in the Part B account of the Supplementary Medical Insurance Trust Fund.



Source: Health Care Spending and the Medicare Program, MedPAC, July 2022

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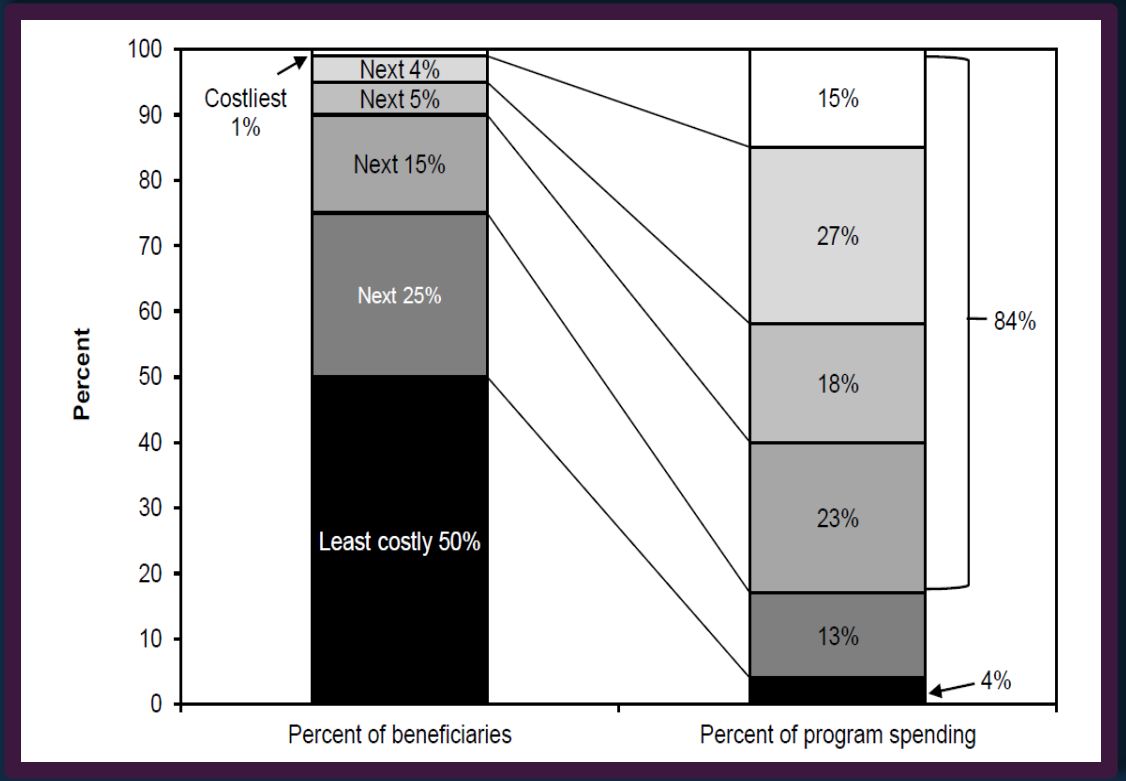
FFS PROGRAM PAYMENTS HIGHLY CONCENTRATED IN SMALL GROUP OF BENEFICIARIES, 2018



Note: FFS (fee-for-service). Analysis excludes beneficiaries with any enrollment in a Medicare Advantage plan or other health plan that covers Part A and Part B services (e.g., Medicare cost plans, Medicare–Medicaid Plans, and Medicare and Medicaid's Program of All-Inclusive Care for the Elderly [PACE]).

Source: Health Care Spending and the Medicare Program, MedPAC, July 2022

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ACRONYMS – "ALPHABET SOUP"

- PFS
- IPPS
- OPPS
- DMEPOS
- DRG
- APC
- CPT
- CLFS
- ACO
- APM
- CMS
- CMMI
- SNF
- HHA
- ESRD
- MA
- MIPS
- MACRA
- FFS
- PPS

AND hundreds more!!

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QUESTIONS?

KIRSTEN TULLIA

Vice President and Acting Head of Payment & Health Care Delivery Policy

ktullia@AdvaMed.org

RICHARD PRICE

Senior Vice President and Head of Research

rprice@AdvaMed.org

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Thank you!

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Introduction to Reimbursement for Medical Technology

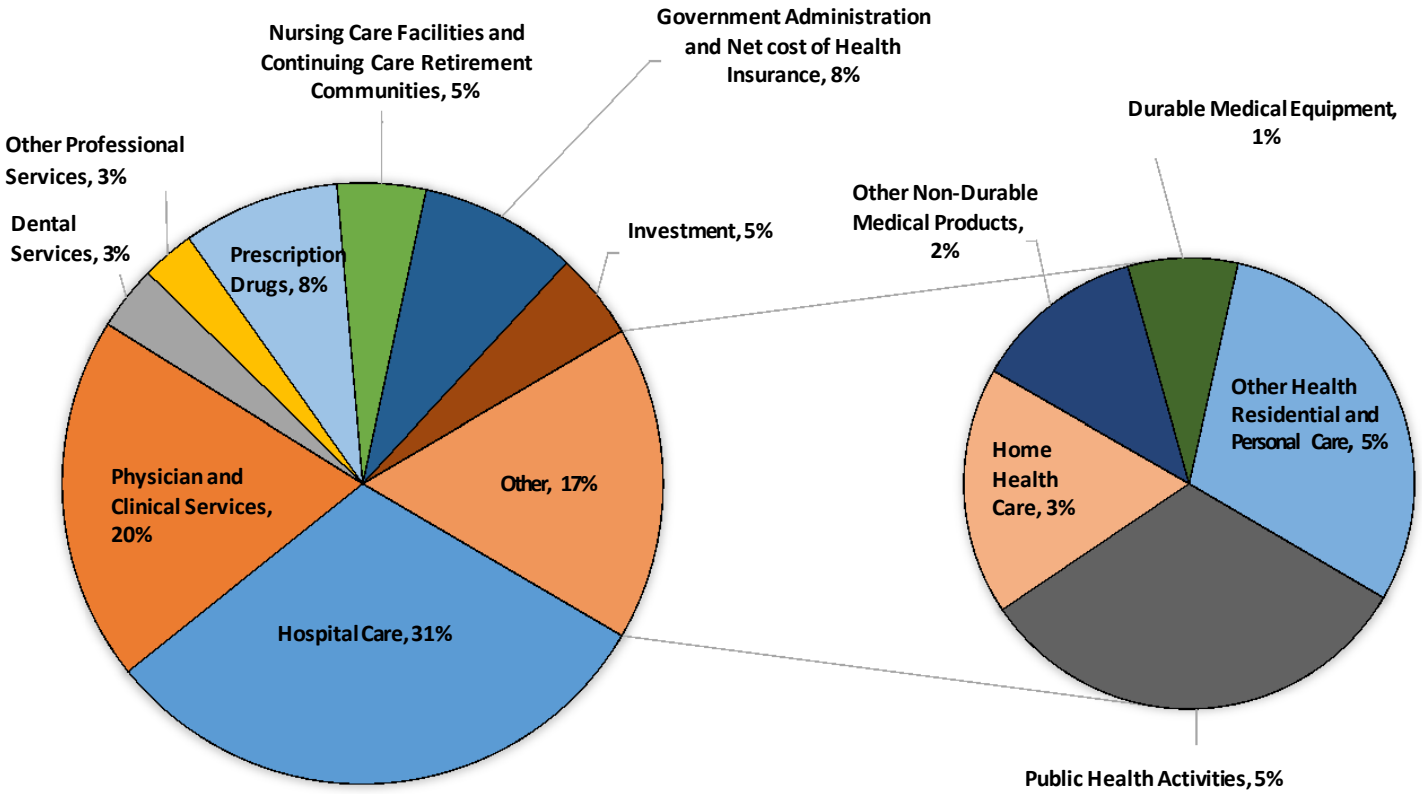
Thomas A. Gustafson, Ph.D.
Senior Policy Advisor
Arnold & Porter

Key Characteristics of Reimbursement

- Reimbursement Actors
- Reimbursement Decisions
- The Wider Environment
- How Does Reimbursement Affect New Technologies?

The Nation's Health Dollar CY 2020
Where It Went

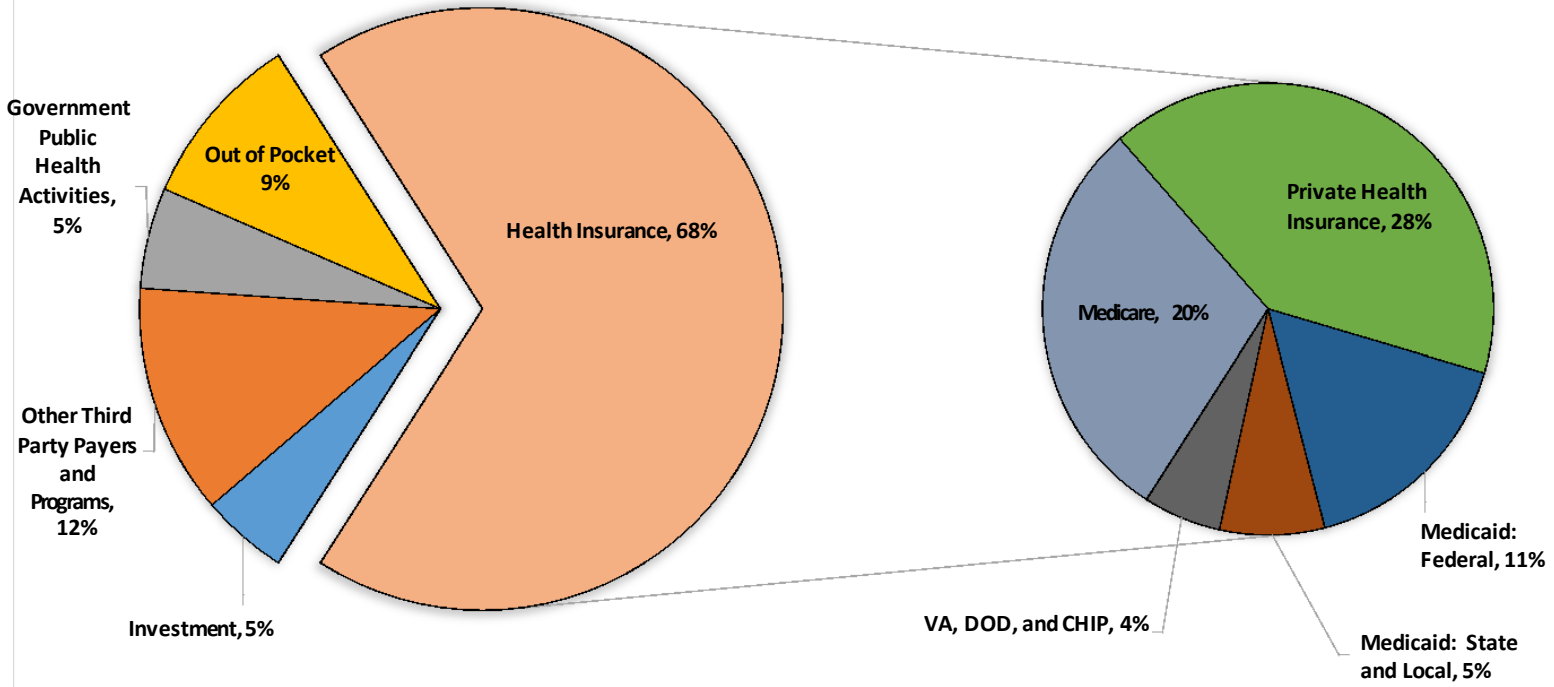
Total = $4.1 trillion



SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group

The Nation's Health Dollar CY 2020
Where It Came From

Total = $4.1 trillion



SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

Decisions: Steps to Medicare FFS Payment

- Benefit Category – is it in the law?
- Coverage – is it "reasonable and necessary" or otherwise covered?
- Coding – how is the claim processed?
- Payment – how much does Medicare pay?

- Is it medically necessary in a particular case?

The Real World Is Not Logical

- Timing does not have to follow this order
  - Some steps may already be complete
  - Steps can be “telescoped” deliberately
- Some steps can be taken, then revised
- Not all steps are necessarily followed before payment flows

Considering New Technology

FDA

Can the technology be marketed?

- Test is whether it is "**safe and effective**"
- One central decision

PAYORS

Will insurance pay, and under what circumstances?

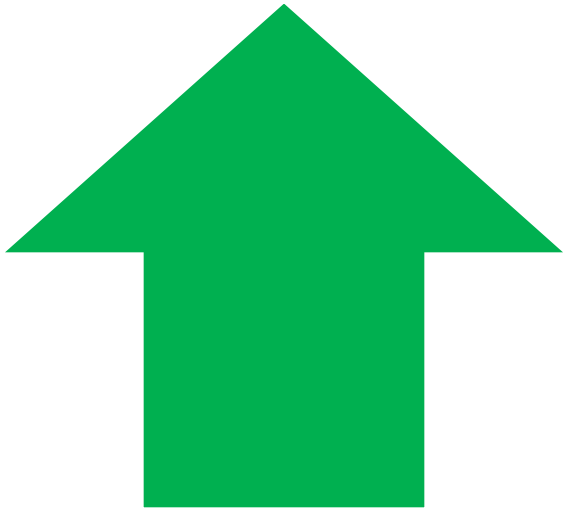
- Medicare's general test: is it "**reasonable and necessary**" for treatment of a disease?
- Other payers make own decisions.

All OK with FDA? → Payors Still Don't Have to Pay

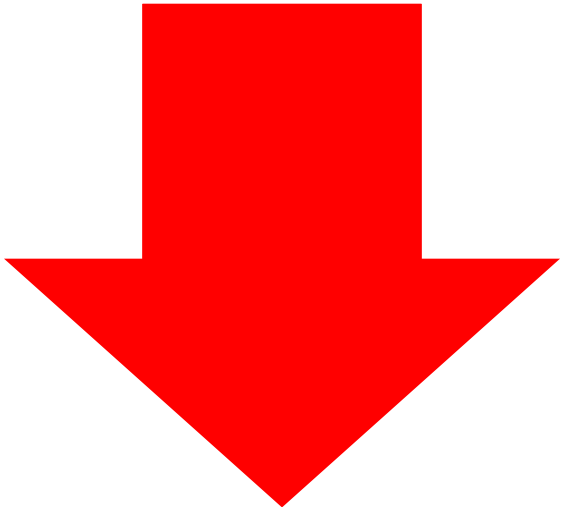
FDA		CMS
Regulator	⟷	Largest payor
Approval/clearance for marketing in the United States	⟷	Determines what Medicare can pay for, and how much
"Safe and effective"	⟷	"Reasonable and necessary"
Evidence of efficacy in tightly controlled settings	⟷	Evidence of effectiveness in clinical practice

Each agency makes decisions on different bases, following different statutes and different timelines

CMS's View of New Technologies



Should Medicare do more to facilitate or even promote use of new technologies to improve access and quality?



Or should Medicare try to restrain use of certain technologies to control costs?

View from Medicare's Executive Suite

- Aggregate spending a giant problem
- Emphasis on providing what's needed
- Control of particular spending is poor
- New technologies? "Yes, if---"
  - Work well in a system of care
  - Prove their worth
  - One watch-word: CMS pays for "care, not tools"

Why Do New Technologies Concern Medicare?

- Fee-for-service care is frequently fragmented
  - Difficult to effectively integrate technology that involves changes in systems of care
- Many innovations that claim to save money cannot document that they do
  - Spend here now, save there later…
  - Absence of direct links in FFS
- "One person's waste is another person's income"

Payment: Concepts and Silos

- Medicare fee-for-service payments are based on average resource consumption
- Not on promoting anything – if anything, strive to be neutral across clinical choices
- Not on "value propositions"
- Changes generally evaluated within a single payment system
- Hard to reflect hypothetical, downstream savings

- -

- Innovations such as the Quality Payment Program and Value-Based Purchasing *tweak* Medicare's payment schemes and shift incentives among providers –
  - But do not yet change the fundamentals of how CMS determines fee-for-service payment rates

The Wider Environment

- Budget concerns and Debt Ceiling -- House GOP pushing for constraints on health spending
- COVID PHE – Winding down, reducing spending for some services; rollback of Medicaid expansion
- Health insurance reform – will the Affordable Care Act come back on the table?
- Baseline: Payors actively pushing innovations in delivery & reimbursement
  - Bundling
  - ACOs and Advance Payment Models
  - Health equity focus at CMS
- Medicare Advantage now ~ 50% of caseload

How Does Reimbursement Affect the Development and Introduction of New Technologies?

- Companies need to map out reimbursement strategies
  - Frequently not done early enough
- Who do you think will pay for your technology? Can they?
- Coverage: What will you have to show? How do you build the data?
- Coding: Existing codes? New codes?
- Payment: What is likely, based on existing rates and practices? Are there opportunities? What threats exist?
- Environment: Will bundles/ACOs/APMs/HMOs make life harder or provide a selling point?

Thank you for your attention

Thomas Gustafson, Ph.D.
Senior Policy Advisor
Arnold & Porter
Thomas.Gustafson@arnoldporter.com
202-942-6570

Introduction to Coding for Medical Technology

Tara Burke, PhD

Vice President, Payment and Healthcare Delivery

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Agenda

- Introduction to coding languages (CPT, ICD-10, HCPCS)
- How codes are used in different settings
- Understand the application process and timelines for key code sets

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Early Planning is Key

FAVORABLE CODING, COVERAGE AND PAYMENT ARE NOT AUTOMATIC

CODING DOES NOT GUARANTEE COVERAGE OR ADEQUATE REIMBURSEMENT

UPFRONT PLANNING NEEDED TO IDENTIFY POTENTIAL ISSUES AND ENHANCE POTENTIAL FOR SUCCESS

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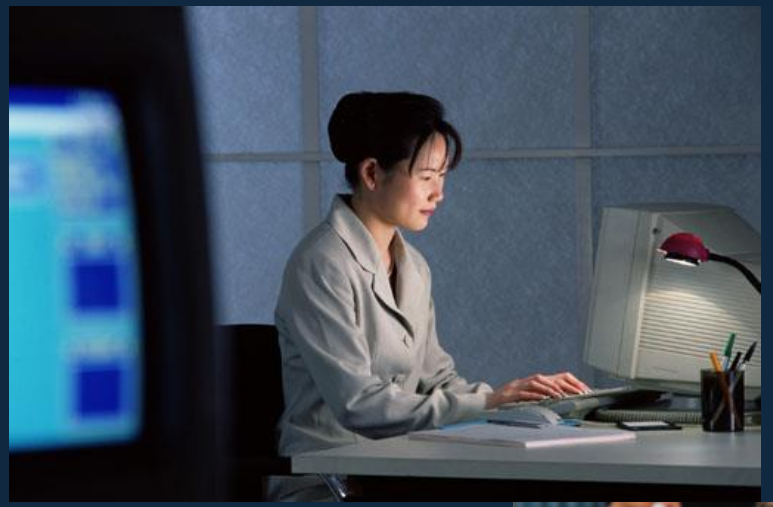
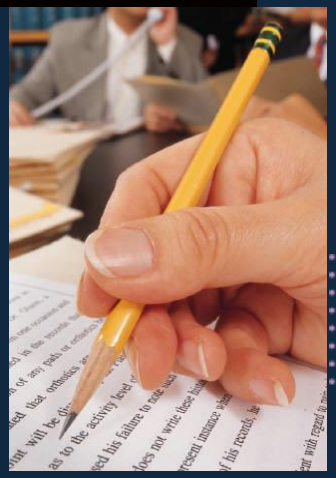
Coding

There are lots of codes

- Diagnosis codes and procedure codes
- Product-specific codes
- Categories of codes
- Levels of codes
- Temporary codes and permanent codes





...and several coding systems

- ICD-10-CM, ICD-10-PCS, CPT, HCPCS

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Coding

- Process of getting a service or procedure an “identifier”, so that use can be tracked, and payment established
- Medicare’s payment system is organized around standard sets of codes that describe services or procedures
- Serves as basis for determining payment
- Many new technologies are described by existing codes and are paid the same as predicate devices
- Some new technologies may warrant differentiation through creation of new codes
  - Only if code does not adequately describe the service or procedure, not because payment is inadequate
- Distinct from coverage; assignment of new code does not imply coverage

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Coding and Payment Systems

Hospital Outpatient	**HCPCS Codes (CPT & C codes)**	**Comprehensive APCs**
Physicians	**CPT Codes**	**Fee Schedule Relative Value Units (RVUs)**
Hospital Inpatient	**ICD-10 CM/PCS**	**Diagnosis Related Groups (DRG)**

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CPT Codes

CPT Coding

- Current Procedural Terminology (CPT) provides a uniform language for reporting diagnosis, services and procedures to third-party payers
- CPT codes are used for reporting services and procedures performed by physicians as well as for reporting services and procedures performed in the hospital outpatient setting under Medicare's outpatient prospective payment system (OPPS)
- Trade names of technology are not included in the coding nomenclature
- CPT Code Set is developed and maintained by the American Medical Association (AMA)

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CPT CODES (CURRENT PROCEDURAL TERMINOLOGY)

- **Two principal categories**

Type of Code	Purpose
Category I	Permanent codes for clinically recognized and accepted services that are assigned values for payment
Category III	Temporary codes for emerging technology, support data collection for services and procedures that do not yet have FDA approval or are not widely used

If no code adequately describes procedure, an "unlisted " code must be used.

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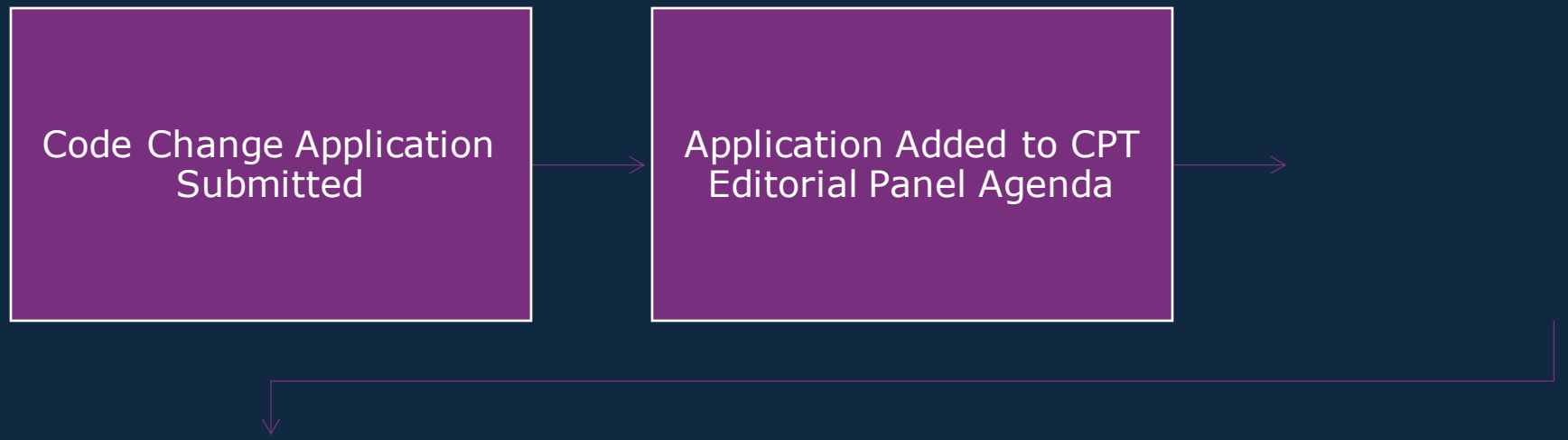
CPT Process and Timeline



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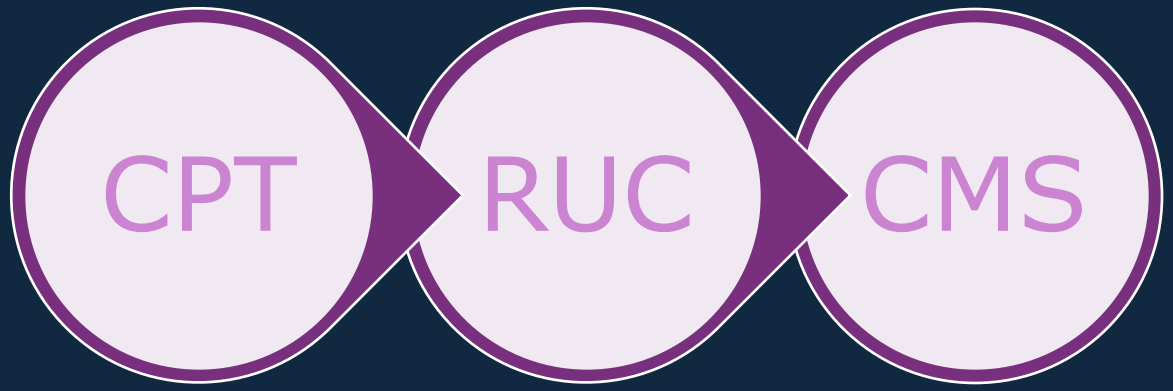
CPT Process and Timeline Cont.



- CPT process is just the first step for new/recently edited Category I codes!
- Codes created by AMA CPT in 2023 will be added to CPT 2025 and and 2025 Medicare Payment Schedule.

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2023 Current Procedural Terminology (CPT®) Code Activity

- 225 New Codes
- 93 Revised Codes
- 75 Deleted Codes

- Total Changes for 2023 = 393
- Total CPT Codes 10,969

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HCPCS Codes

HEALTHCARE COMMON PROCEDURE CODING SYSTEM – HCPCS LEVEL II CODES

- HCPCS - Level II is a standardized coding system
- Maintained by CMS
- Identifies products, supplies and services not included in CPT
  - Drugs
  - Orthotics
  - Prosthetics
  - Durable Medical Equipment
  - Medical Surgical Supplies
  - Outpatient PPS (C Codes)
- Nationally recognized
  - Alpha Numeric codes
  - Accepted by public and private payers

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HCPCS Level II Public Meeting

- Applications submitted via the MEARIS online system
- Prior to the meeting, a written overview of each applicant's request, CMS' preliminary coding recommendation, as well as CMS' preliminary benefit category and payment determination, if applicable, is provided.
- Each application is reviewed during the meeting with speaker presentations followed by an opportunity for questions regarding that particular agenda item
- Final decisions are not made at the public meeting and are released by CMS on their website afterwards.

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Biannual HCPCS Level II Timeline

	Application Deadline	Preliminary Decisions Released	Public Meeting	Publication of Final Decisions	Codes Effective for Medicare
Coding Cycle 1	First business day in January	Approx. two weeks prior to pubic meeting	June (dates to be announced in Fed Reg)	July of same year*	October
Coding Cycle 2	First business day in July	Approx. two weeks prior to public meeting	Nov/Dec (dates to be announced in Fed Reg	January of following year*	April of following year

**CMS does not always meet this deadline. For example, for 2022 coding cycle 2 decisions were released in March of 2023, not January.*

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ICD Codes

ICD-10-CM- International Classification of Diseases Clinical Modification
ICD 10-PCS - Procedure Coding System

- Two principal categories

Type of Code	Purpose
Diagnosis	Used by all health care providers to substantiate need for patient care or treatment
Procedure	Used in hospital inpatient setting to report services or procedures performed

- Payers “link” or match diagnosis code with service or procedure performed to establish medical necessity

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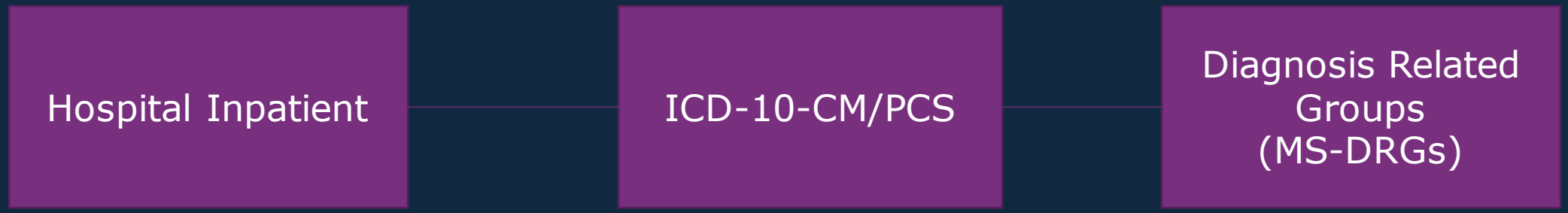
Coding and Payment Systems Hospital Inpatient



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International Classification of Diseases Tenth Version, Clinical Modification ICD-10-CM
ICD-10-PCS Procedure Coding System (PCS)

- Two national coding systems have direct influence on Medicare payment:
  - International Classification of Diseases ICD-10 CM principal system for coding diagnoses and conditions
    - Maintained by the National Center for Health Statistics, Centers for Disease Control and Prevention (CDC)
  - ICD-10-PCS Procedure Coding System (PCS) principal system for coding inpatient procedures
    - Includes procedures codes which are used by hospitals to describe services provided
    - Maintained by the Centers for Medicare and Medicaid Services (CMS)

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Example -Use of Diagnosis Code

- ICD-10 CM codes listed in coding and billing articles of Medicare local coverage determinations (LCDs)

ICD-10-CM Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes: (22 Codes)

CODE	DESCRIPTION
D22.0	Melanocytic nevi of lip
D22.10	Melanocytic nevi of unspecified eyelid, including canthus
D22.111	Melanocytic nevi of right upper eyelid, including canthus
D22.112	Melanocytic nevi of right lower eyelid, including canthus
D22.121	Melanocytic nevi of left upper eyelid, including canthus
D22.122	Melanocytic nevi of left lower eyelid, including canthus
D22.20	Melanocytic nevi of unspecified ear and external auricular canal
D22.21	Melanocytic nevi of right ear and external auricular canal
D22.22	Melanocytic nevi of left ear and external auricular canal
D22.30	Melanocytic nevi of unspecified part of face
D22.39	Melanocytic nevi of other parts of face
D22.4	Melanocytic nevi of scalp and neck
D22.5	Melanocytic nevi of trunk
D22.60	Melanocytic nevi of unspecified upper limb, including shoulder
D22.61	Melanocytic nevi of right upper limb, including shoulder
D22.62	Melanocytic nevi of left upper limb, including shoulder
D22.70	Melanocytic nevi of unspecified lower limb, including hip

Review of ICD-CM for New Medical Technology

- What disease state does the new medical technology treat?
- What are the potential complications that can occur when utilizing the new medical technology (e.g., medical complications such as infection)?
- What patient populations will the new technology serve (e.g., children, elderly) and what are the typical comorbidities of these patient populations?
- What are specific characteristics of the new medical technology (e.g., a right or left sided device) and is the new technology used on a specific body part?

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Review of ICD-PCS for New Medical Technology

- What definitive procedure will be performed?
- What is the actual approach for the procedure (e.g., laparoscope, open, or percutaneous)?
- On what exact body part will the procedure be performed?
- Is the technology an implantable device or is it a topical application?
- Is the procedure always the primary procedure performed or is it commonly performed as a secondary procedure?

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Process for Requesting New/Revised ICD-10 PCS Codes

- ICD-10 Coordination and Maintenance (C&M) Committee is the public forum on ICD-10 and ICD-10 PCS.
  - Co-operated by CMS and CDC National Center for Health Statistics
  - Application for ICD-PCS submitted through MEARIS
- There are two C&M meetings a year and codes are updated biannually (April and October)
  - Codes to implemented in October are published in the IPPS final rule in August.
- Enlist appropriate professional medical society in process.

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Early Planning is Key

FAVORABLE CODING, COVERAGE AND PAYMENT ARE NOT AUTOMATIC

CODING DOES NOT GUARANTEE COVERAGE OR ADEQUATE REIMBURSEMENT

UPFRONT PLANNING NEEDED TO IDENTIFY POTENTIAL ISSUES AND ENHANCE POTENTIAL FOR SUCCESS

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Take Home Messages

- Review existing code sets to see if they pertain to the new technology.
- Take time to observe meetings now! Review recordings or sign up to attend a current meeting.
- If a new code is needed, start early! Each code set process is lengthy and is unique. Build code set application timelines into your technology launch process to ensure appropriate codes are in place when the technology is launched.
- Professional medical specialty society engagement is key!

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Questions/Comments

tburke@advamed.org

Introduction to Medicare Payment Systems

Medtech Coverage, Coding and Reimbursement 101

Prepared for AdvaMed

April 18, 2023

mcdermottplus.com

McDermott+ Consulting

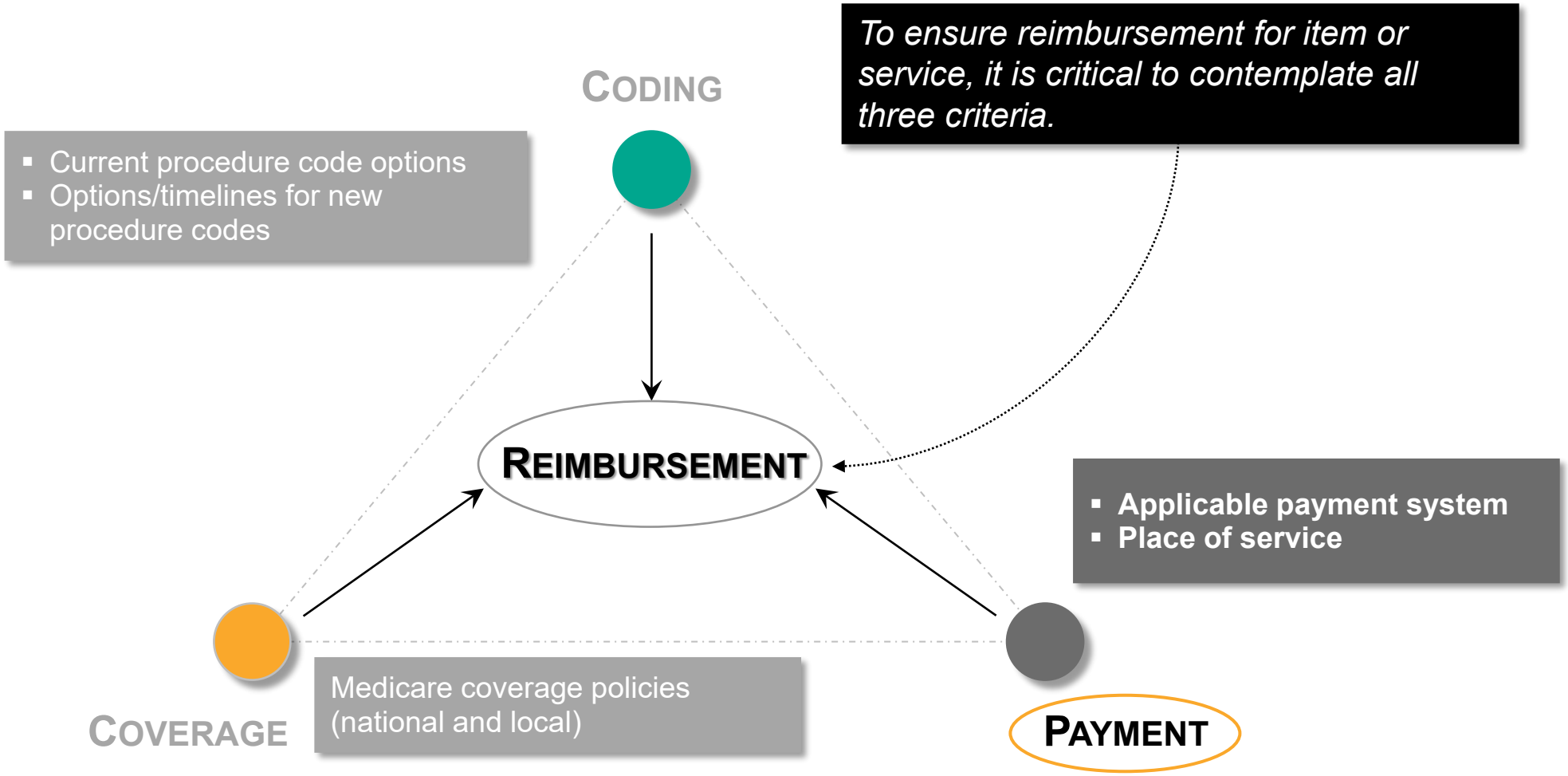
AGENDA

- Introduction
- Payment Basics
- Key Medicare Payment Systems
  - Inpatient hospital
  - Outpatient hospital
  - Physician fee schedule
- Open Discussion / Questions & Answers

INTRODUCTION

Payment Basics

Reimbursement Criteria



KEY TERMINOLOGY

APC	Ambulatory Payment Classification
ASC	Ambulatory Surgical Center
DRP	Device Related Portion
IPPS	Acute Inpatient Prospective Payment System
MS-DRG	Medicare Severity Diagnosis Related Group
OPPS	Hospital Outpatient Prospective Payment System
PE	Practice Expense
PFS	Physician Fee Schedule
PPS	Prospective Payment System
RVU	Relative Value Unit

KEY PAYMENT CONCEPTS

Reimbursement is related to the *specific resources typically required to furnish* the service to the patient, not tied to the *economic "value" of the service*

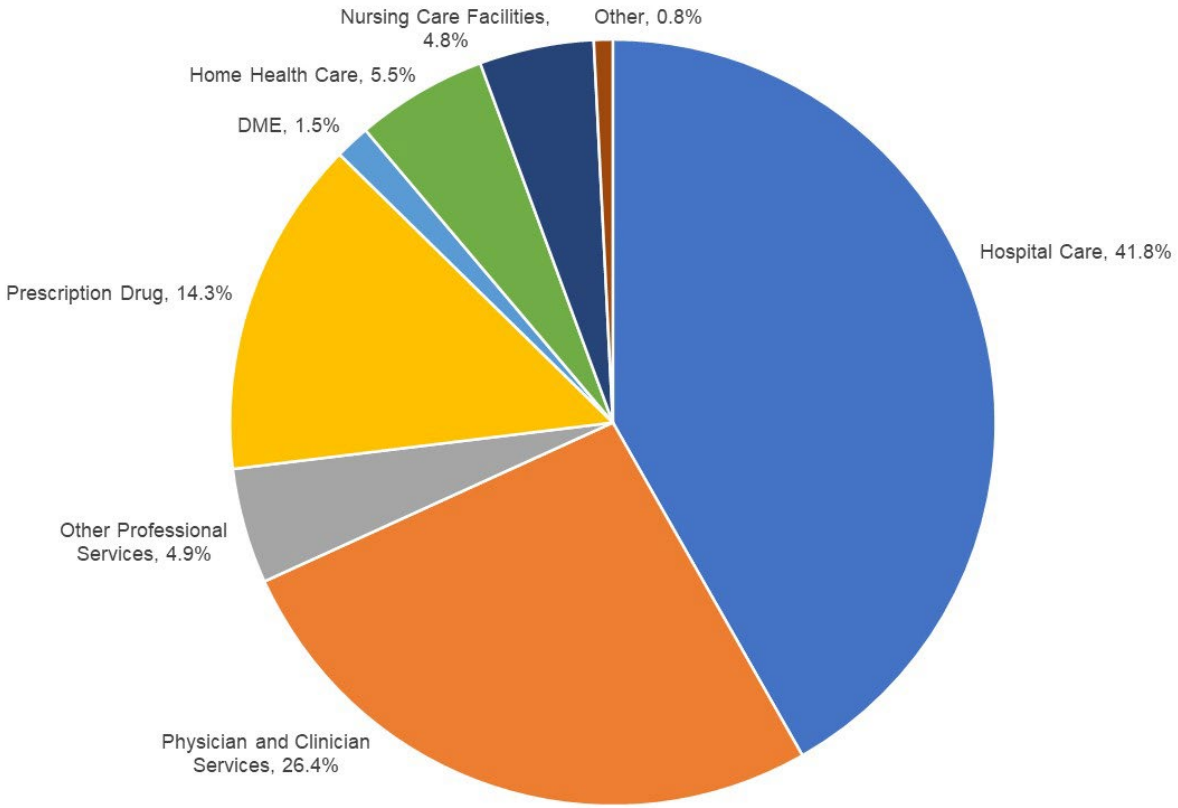
Methodology for calculating the reimbursement rate for the service furnished varies depending on:

- *Site of service* (e.g., inpatient, hospital outpatient, ASC, or physician office)
- *Type of technology* (e.g., medical device, diagnostic, prescription drug, durable medical equipment)

For medical devices, reimbursement typically *tied to the underlying service* in which the device is used

Reimbursement rate may also be *adjusted by other factors* (e.g., geographic, performance in quality programs)

Medicare Spending by Type of Service, 2021



Medicare spending on medical devices captured in numerous categories:

- Hospital care
- Physician and clinical services
- Other professional services
- DME

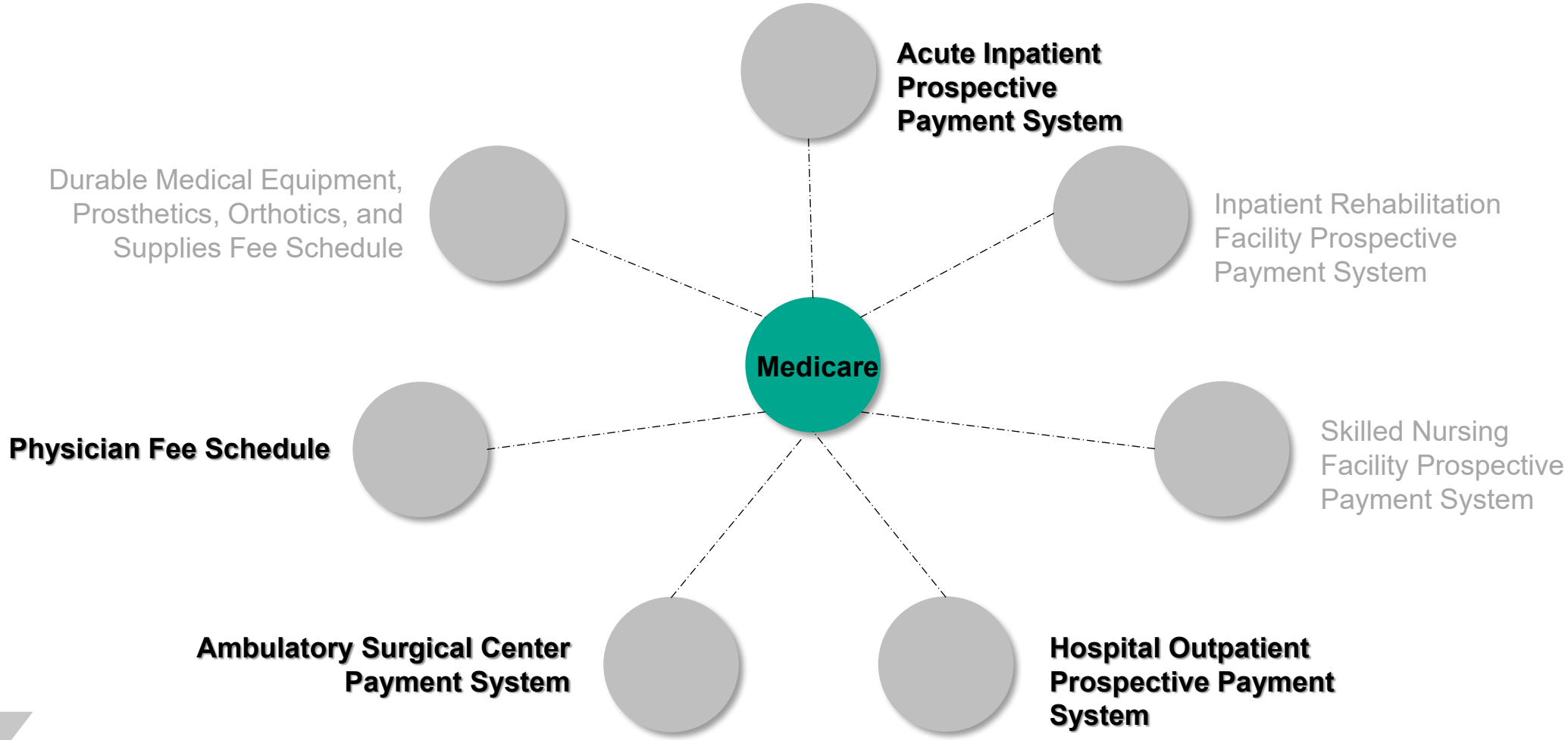
Source: National Health Expenditure Data (www.cms.gov)

Key Medicare Payment Systems

mcdermottplus.com

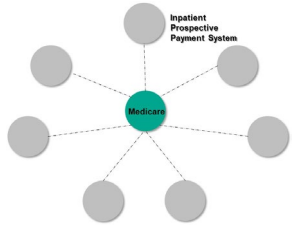
McDermott+ Consulting

Overview of Medicare Payment Systems



Medicare Payment Systems

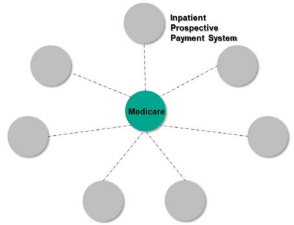
Acute Inpatient Prospective Payment System



- Reimbursement for services furnished to patients in an acute inpatient hospital setting
- Payment based on the diagnosis code(s) and procedure code(s) reported by the hospital which are then categorized into Medicare severity-diagnosis related groups (MS-DRG)
  - Single payment for all services furnished during the hospital stay
- Medicare Severity-Diagnosis Related Groups (MS-DRG)
  - Classification based on diagnoses (principal and secondary) and procedures performed
  - Appreciating the variability in patients, MS-DRGs may also have further differentiation based on the presence or absence of complications or co-morbidities (CC and MCC)
- CMS updates the IPPS on an annual basis in rulemaking
  - Payment rates updated using historical claims data (two years prior)
  - Operational base rates and MS-DRG weights from which to calculate rates are published in rule
  - Rule is also a vehicle for implementing new payment policies
  - Opportunity for stakeholders to submit comments on proposed changes and it is critical to engage in order to inform CMS on the potential impact of policies

Medicare Payment Systems

Acute Inpatient Prospective Payment System



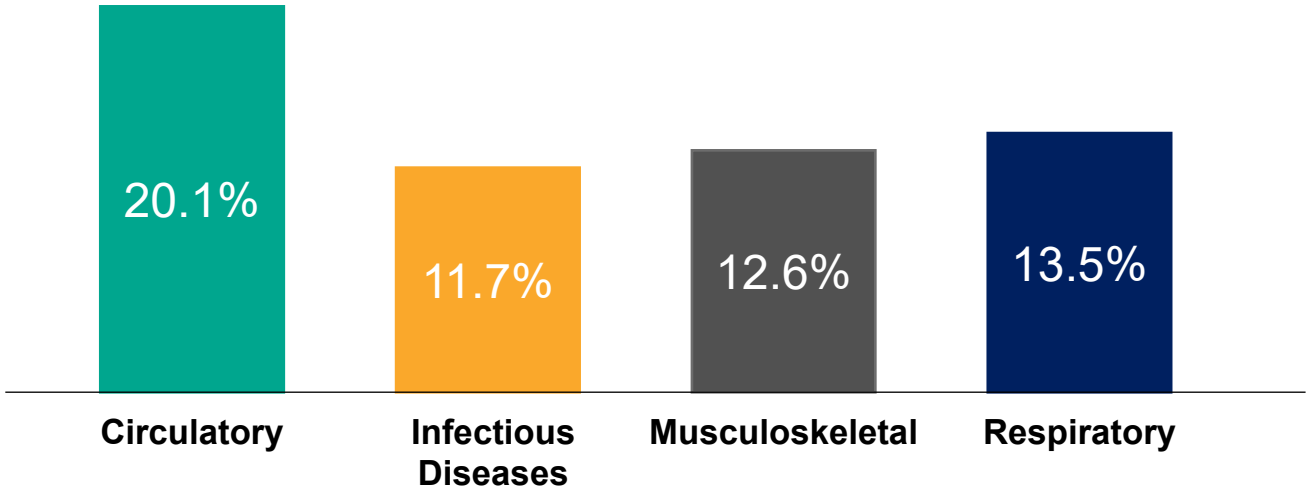
Acute IPPS, Fiscal Year 2021

- Total hospitals: 3,170
- Fee-for-service inpatient stays: 7.1 million
- Total payments: $107.9 billion

Examples

- Circulatory: Heart failure, cardiac arrhythmia
- Infectious Diseases: Septicemia
- Musculoskeletal: Joint replacements
- Respiratory: COVID-19, Chronic Obstructive Pulmonary Disease

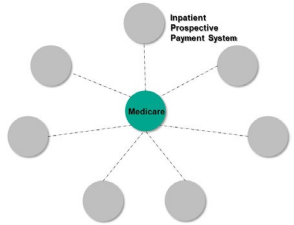
Top four major diagnostic categories accounted for nearly 60% of inpatient stays for FY 2020



Source: MedPAC March 2023 Report to Congress

Medicare Payment Systems

Acute Inpatient Prospective Payment System



Payment Rate Methodology

Base Rate x **MS-DRG Weight** + **Payment adjustments** = **Payment Rate**

Operating and non-labor portion adjusted for geographic factors

Reflective of patient characteristics

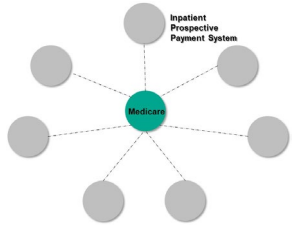
Examples (not all-inclusive)
- Uncompensated care
- Indirect medical education
- Transfers
- New technology add-on

Applicability to Medical Devices

- Charges associated with medical devices included in the claim submission but no separate payment for the device
- Pathway for incremental payment for new technologies including devices
  - New-technology add-on payment (annual application)

Medicare Payment Systems

Acute Inpatient Prospective Payment System



- For FY 2024, CMS has 766 proposed MS-DRGs
- MS-DRGs for comorbidities or major comorbidities have higher payment rates

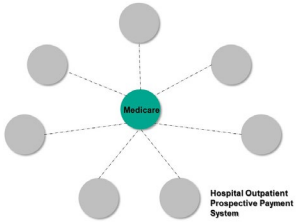
Examples

Procedure / Condition	MS-DRG	Type	Severity	FY 2024 Proposed	FY 2023 Actual
Lung Transplant	007	Surgical		$86,529.74	$83,736.34
Intracranial Hemorrhage	064	Medical	MCC	$14,037.06	$13,526.99
	065	Medical	CC	$7,128.20	$6,972.026
	066	Medical	No CC/MCC	$4,821.50	$4,791.38
Pacemaker	242	Surgical	MCC	$24,396.47	$23,826.58
	243	Surgical	CC	$16,126.53	$16,078.74
	244	Surgical	No CC/MCC	$12,976.86	$13,040.65
Major Hip or Knee Joint Procedure	469	Surgical	MCC	$23,627.33	$22,165.89
	470	Surgical	No MCC	$13,358.62	$13,114.74
Mastectomy	582	Surgical	CC/MCC	$11,758.48	$13,271.82
	583	Surgical	No CC/MCC	$10,636.41	$10,363.38
Radiotherapy	849	Medical		$18,940.11	$16,043.75

Source: FY 2024 IPPS Proposed Rule (CMS-1785-P)

Medicare Payment Systems

Hospital Outpatient Prospective Payment System

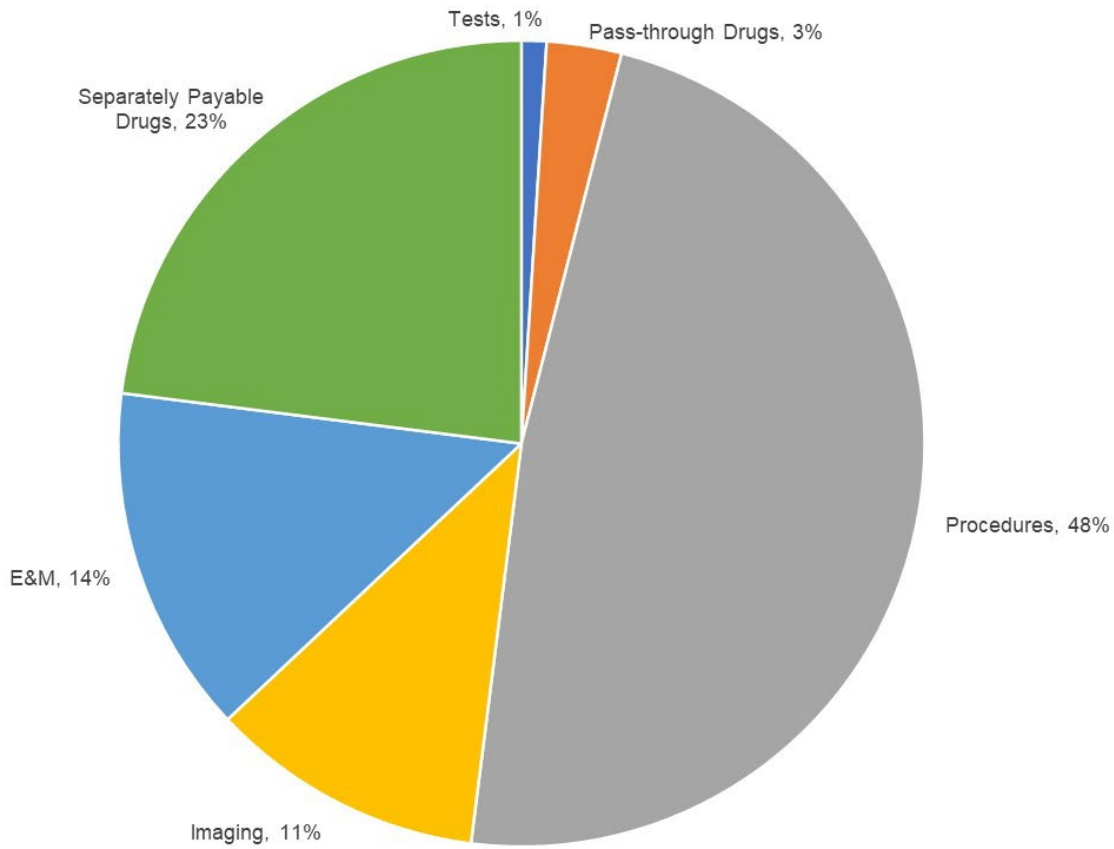


- Reimbursement for services furnished to patients in the hospital outpatient setting
- Payment based on the HCPCS code(s) reported by the hospital which are then categorized into ambulatory payment classification (APC)
  - Devices reported with a HCPCS code (e.g., C codes) in conjunction with the procedure code
    - HCPCS codes are category specific, not specific to a manufacturer (*e.g.*, C1820 Generator, neurostimulator (implantable), with rechargeable battery and charging system)
- Ambulatory Payment Classifications
  - Classification of HCPCS codes based on resource and clinical similarities
  - All services within an APC have the same payment rate
- CMS updates the OPPS on an annual basis in rulemaking
  - Payment rates updated using historical claims data (two years prior)
  - Rule is also a vehicle for implementing new payment policies
  - Opportunity for stakeholders to submit comments on proposed changes and it is critical to engage in order to inform CMS on the potential impact of policies

Medicare Payment Systems

Hospital Outpatient Prospective Payment System

Hospital Outpatient PPS Payments by Type of Service, CY 2020



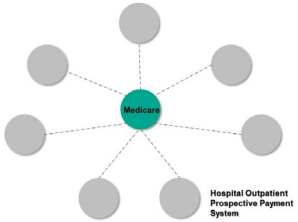
Categories

- Procedures (e.g., medical or surgical)
- Tests (e.g., clinical diagnostic laboratory tests)
- Evaluation and management
- Imaging
- Drugs
  - Separately payable
  - Pass-through

Source: MedPAC Data Book, July 2022

MEDICARE PAYMENT SYSTEMS

Hospital Outpatient Prospective Payment System



Payment Rate Methodology

Conversion Factor x **APC Relative Weight** + **Payment adjustments (Select hospitals)** = **Payment Rate**

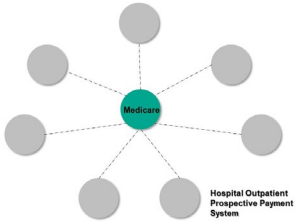
- Conversion Factor: Set by CMS each calendar year as part of annual rulemaking cycle
- APC Relative Weight: Measures resource requirements for services
- Payment adjustments (Select hospitals):
  - Pass-through payments for new technology
  - Outlier payments
  - Payment adjustments for certain hospital types

Device-Related Calculations

- Costs reported for devices used to calculate the device-related portion (DRP) at procedure level
- Device related portion (%) used by CMS in the application of different payment policies
  - Partial and no cost devices
  - Transitional pass-through payment

Medicare Payment Systems

Hospital Outpatient Prospective Payment System

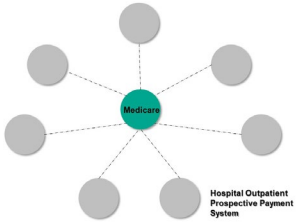


Category	APC	Description	2023 National Payment	# of Procedures in APC
Musculoskeletal	5111	Level 1 Musculoskeletal Procedures	$ 207.01	101
	5112	Level 2 Musculoskeletal Procedures	$ 1,434.52	133
	5113	Level 3 Musculoskeletal Procedures	$ 2,976.66	405
	5114	Level 4 Musculoskeletal Procedures	$ 6,614.63	333
	5115	Level 5 Musculoskeletal Procedures	$ 13,048.08	78
	5116	Level 6 Musculoskeletal Procedures	$ 21,897.63	17
ICD and Similar Procedures	5231	Level 1 ICD and Similar Procedures	$ 22,818.32	9
	5232	Level 2 ICD and Similar Procedures	$ 32,076.33	6
Lower GI Procedures	5311	Level 1 Lower GI Procedures	$ 831.04	29
	5312	Level 2 Lower GI Procedures	$ 1,082.91	51
	5313	Level 3 Lower GI Procedures	$ 2,569.47	56

Source: CY 2023 OPPS Final Rule Addenda A and B (CMS-1772-F)

Medicare Payment Systems

Hospital Outpatient Prospective Payment System

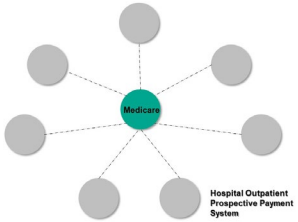


CPT	Description	APC	2023 National Payment	DRP
21480	Reset dislocated jaw	5111	$ 207.01	
21502	Drain chest lesion	5113	$ 2,976.66	
21600	Partial removal of rib	5114	$ 6,614.63	
21610	Partial removal of rib	5113	$ 2,976.66	
22612	Arthrd pst tq 1ntrspc lumbar	5116	$ 21,897.63	$ 11,745.89
22614	Arthrd pst tq 1ntrspc ea addl		$ 0.00	
33230	Insrt pulse gen w/dual leads	5231	$ 22,818.32	$ 16,739.52
33231	Insrt pulse gen w/mult leads	5232	$ 32,076.33	$ 23,810.26
44389	Colonoscopy with biopsy	5312	$ 1,082.91	
44390	Colonoscopy for foreign body	5311	$ 831.04	$ 360.26
45100	Biopsy of rectum	5313	$ 2,569.47	

Source: CY 2023 OPPS Final Rule Addenda B and P (CMS-1772-F)

Medicare Payment Systems

Hospital Outpatient Prospective Payment System

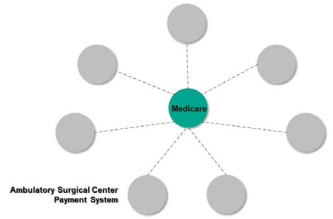


Incorporating new technologies

- Technologies not reimbursed on their own but rather as part of a procedure
- If new procedure code obtained for service in which technology is used, CMS initially assigns new code to APC based on clinical similarities and resources used
  - Opportunity to engage with CMS to provide recommendations for APC assignment
  - Submit comments as part of rule-making cycle for initial APC assignment
- After two years, CMS has claims for the new code that can either confirm APC assignment or determine new APC assignment
- Where no appropriate APC, companies may seek assignment to a new technology APC
  - Assignment based on cost band not clinical similarities

Medicare Payment Systems

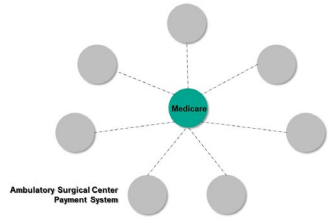
Ambulatory Surgical Center Payment System



- Reimbursement for services furnished to patients in the ASC
- Payment based on the HCPCS code(s) reported by the ASC
  - ASC rates are based on the hospital outpatient payment rates but paid at a lower percentage
  - Devices reported with a HCPCS code (e.g., C codes) in conjunction with the procedure code
    - HCPCS codes are category specific, not specific to a manufacturer (*e.g.*, C1820 Generator, neurostimulator (implantable), with rechargeable battery and charging system)
- Only subset of procedures permitted in hospital outpatient setting are permitted in ASC
  - Annual process to request procedures to be added to the ASC Covered Procedures List (CPL)
- CMS updates the ASC on an annual basis in OPPS rulemaking
  - Payment rates updated using historical claims data (two years prior)
  - Rule is also a vehicle for implementing new payment policies
  - Opportunity for stakeholders to submit comments on proposed changes and it is critical to engage in order to inform CMS on the potential impact of policies

Medicare Payment Systems

Ambulatory Surgical Center Payment System

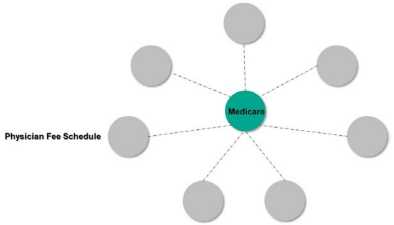


CPT	Description	APC	2023 OPPS National Payment	2023 ASC PS National Payment	Ratio: ASC / OPPS
21480	Reset dislocated jaw	5111	$ 207.01	$ 107.79	52.1%
21502	Drain chest lesion	5113	$ 2,976.66	$ 1,414.89	47.5%
21600	Partial removal of rib	5114	$ 6,614.63	$ 3,138.05	47.4%
21610	Partial removal of rib	5113	$ 2,976.66	$ 1,414.89	47.5%
22612	Arthrd pst tq 1ntrspc lumbar	5116	$ 21,897.63	$ 15,901.33	72.6%
22614	Arthrd pst tq 1ntrspc ea addl		$ 0.00	$ 0.00	
33230	Insrt pulse gen w/dual leads	5231	$ 22,818.32	$ 19,717.71	86.4%
33231	Insrt pulse gen w/mult leads	5232	$ 32,076.33	$ 25,822.58	80.5%
44389	Colonoscopy with biopsy	5312	$ 1,082.91	$ 536.86	49.6%
44390	Colonoscopy for foreign body	5311	$ 831.04	$ 605.39	72.8%
45100	Biopsy of rectum	5313	$ 2,569.47	$ 1,234.85	48.1%

Source: CY 2023 OPPS Final Rule Addenda B and CY 2023 ASC PS Final Rule Addendum AA

Medicare Payment Systems

Physician Fee Schedule

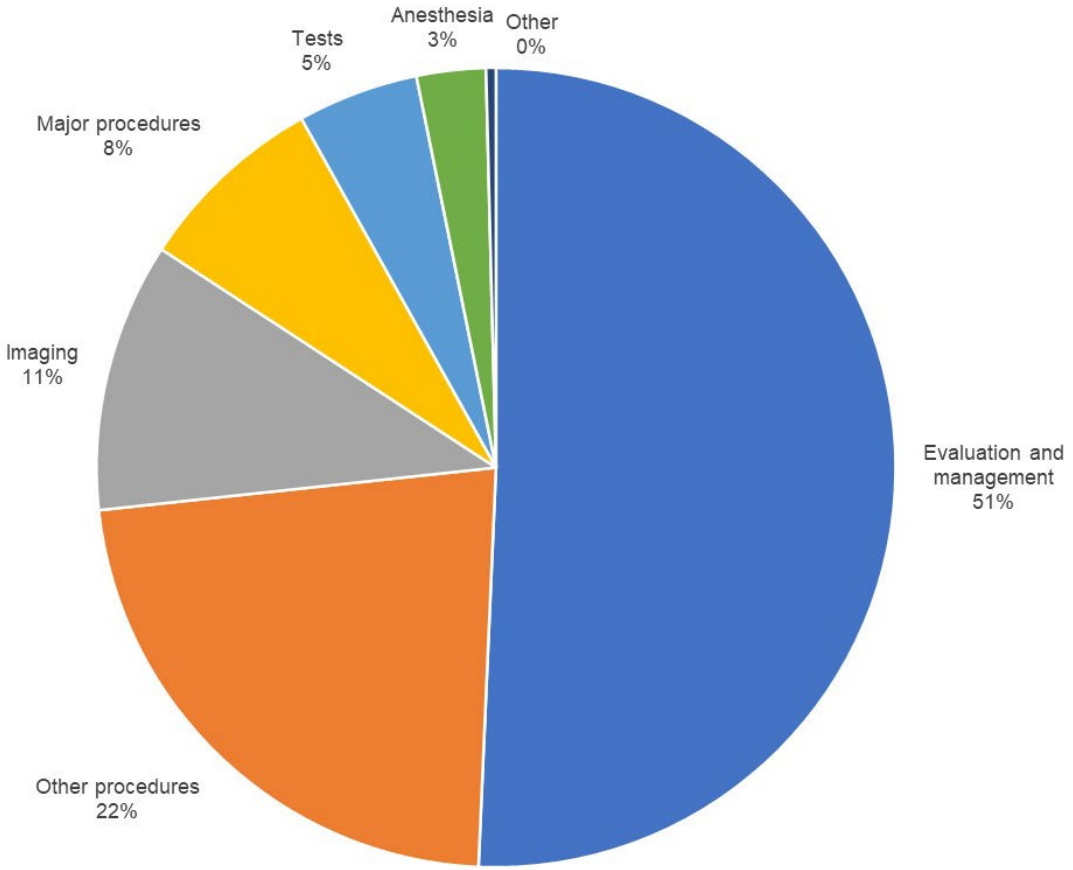


- Reimbursement for office visits, surgical procedures, diagnostic and therapeutic services furnished in all settings including physician clinics, hospital outpatient departments, and ASCs
- Payment based on the HCPCS code(s) reported by the physician or clinician
  - Procedure or service payment rate based on relative value units assigned to the HCPCS code
- Relative value units (RVUs) for each HCPCS code
  - Work (reflective of physician work)
  - PE (practice expense inputs used in the furnishing of the service and running the office)
  - Malpractice
- CMS updates the PFS on an annual basis in rulemaking
  - Payment rates updated based on changes to RVU and conversion factor
  - Fee schedule must maintain budget neutrality
  - Changes in rates from year to year may be due to change in RVU and/or conversion factor
  - Opportunity for stakeholders to submit comments on proposed changes and it is critical to engage in order to inform CMS on the potential impact of policies

Medicare Payment Systems

Physician Fee Schedule

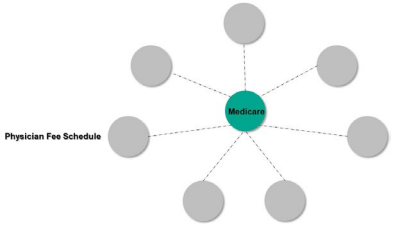
Physician Fee Schedule Allowed Charges by Type of Service, CY 2020



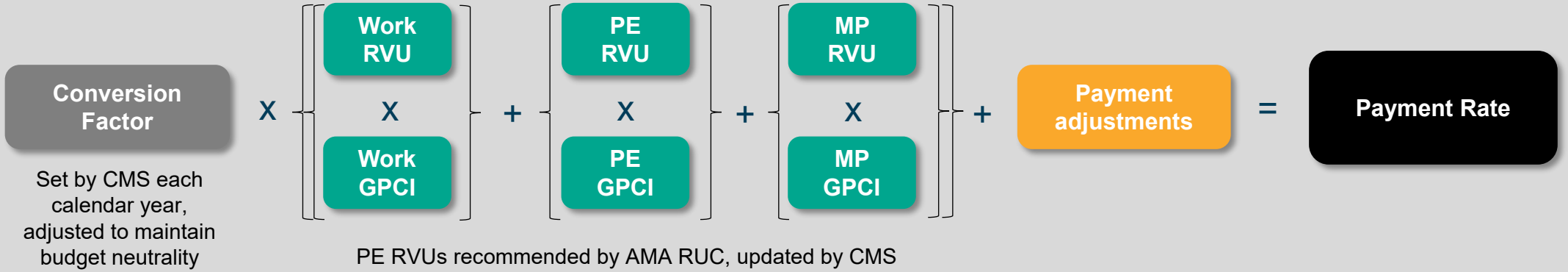
Source: MedPAC Data Book, July 2022

Medicare Payment Systems

Physician Fee Schedule



Payment Rate Methodology



Physician Fee Schedule Total Payments

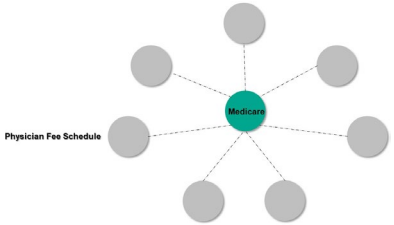
- Care furnished in non-facility setting (e.g., office): PFS payment represents payment in its entirety
- Care furnished in facility setting (e.g., hospital): PFS payment plus facility payment equals rate in its entirety

Device-Related Components

- Costs for device captured (if at all) in the practice expense inputs (PE) in supplies or equipment
- Devices reflected in the PE input are the typical case
- Opportunity to submit invoices to CMS to update the pricing of the practice expense input

Medicare Payment Systems

Physician Fee Schedule



Illustrative Examples

Code	Descriptor	Work	Non-facility PE RVU	Facility PE RVU	MP RVU	Non-facility Payment	Facility Payment
37246	Trluml balo angiop 1st art	7.00	46.47	1.86	1.26	$ 1,845.65	$ 324.94
99454	Rem mntr physiol param dev	0.00	1.47	NA	0.01	$ 50.15	$ 0.00

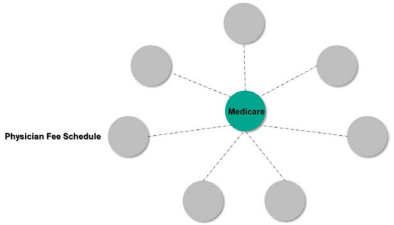
Source: April 2023 Physician Fee Schedule Relative Value File

PE Supplies: 42 items
PE Equipment: 6 items (including angiography room priced at ~$1.2 M)
PE Clinical Labor: 3 technicians (RN/LP/MTA, RN, and Radiologic Technologist)

PE Supplies: None
PE Equipment: 1 item (heart failure physiological monitoring equipment priced at $1,000)
PE Clinical Labor: None

Medicare Payment Systems

Physician Fee Schedule

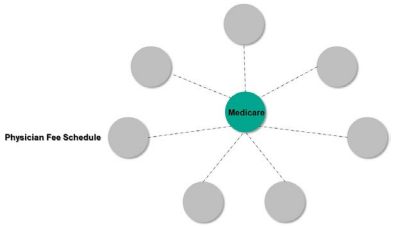


Incorporating new technologies

- Technologies not reported on their own but rather as part of a procedure
- If new procedure code obtained for service in which technology is used, code goes through a valuation to determine RVUs for “typical” patient
  - Recommendations from American Medical Association Relative Value Scale Update Committee (RUC)
  - Final decisions based on CMS review and assessment
  - Valuations published as part of rule-making cycle
- Opportunity to submit invoices to CMS for review and consideration to update price for relevant practice expense input

Medicare Payment Systems

Physician Fee Schedule



Reimbursement Challenges

- Valuation of a code involves significant input from multiple stakeholders including AMA, healthcare professionals, and CMS
- Stakeholders eager to maintain their relative value units, particularly their work RVUs
  - Valuation of a new code through the AMA RUC process often involves not only that code but the family of codes in which it sits
  - Review of codes by the RUC often leads to a lower work RVU = lower payment rate
- Annual updates to Physician Fee Schedule different than other payment systems
  - No inflationary update
  - Not based on historical claims data
  - No separate pathway for incremental payment for new technology
- Budget neutrality impact
  - Any policy changes where expenditures from prior year differs by more than $20 M = budget neutrality adjustment
  - Payment impacted not only by direct policies but indirectly due to budget neutrality

Questions & Answers

McDermott+ Consulting

Thank you for your participation and for your questions.

Deborah Godes
Vice President, McDermott+Consulting
dgodes@mcdermottplus.com

Complexities of CMS Coverage

AdvaMED Workshop

April 19, 2023

Health Policy Alternatives, Inc.

Marjorie Kanof, MD, MPH Principal

Marc Hartstein, Principal

Complexities of CMS Coverage- Overview

- Requirements
- National Coverage Decisions
  - Coverage with Evidence Development
  - AHRQ Report
  - MEDCAC on CED
- "Vision" of coverage for new and emerging technologies

Requirements to Obtaining Medicare Coverage for an Item or Service in FFS

- First, item or service must have a Medicare benefit category
- Second, item or service must not be excluded from coverage
- Third, item or service must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”

Step 1: Medicare is a "Defined Benefit Category" Program

- For Medicare to pay for any item or service, it must have a benefit category in the Medicare statute.
- Common benefit categories:
  - Inpatient Hospital Services (Part A)
  - Physicians' Services (Part B)
  - Part B Drug "Incident to" a physician's service
  - Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist
  - Marriage and Family Therapists and Mental Health Counselors added by CAA, 2023
  - Influenza, pneumococcal, Hepatitis B vaccines and their administration
  - Colon cancer screening
  - Annual wellness exam
  - And many more…

Step 2: Is the item or service excluded from coverage?

- Examples of items excluded from coverage by statute:
  - Services provided outside of the United States
  - Eyeglasses or eye examinations for the purpose of prescribing, fitting or changing eyeglasses or determining the refractive state of the eyes
  - Hearing aids or "examinations therefor"
  - Care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth…

Step 3: Is the item or service "reasonable and necessary"?

- Is there a *national* coverage determination that either non-covers the item or service or limits coverage to particular circumstances?
- Is there a *local* coverage determination that either non-covers the item or service or limits coverage to particular circumstances?
- In the absence of a national or local coverage determination, the item or service is covered unless determined upon medical review that the item or service was not medically necessary in that instance.

Coverage of Preventive Services

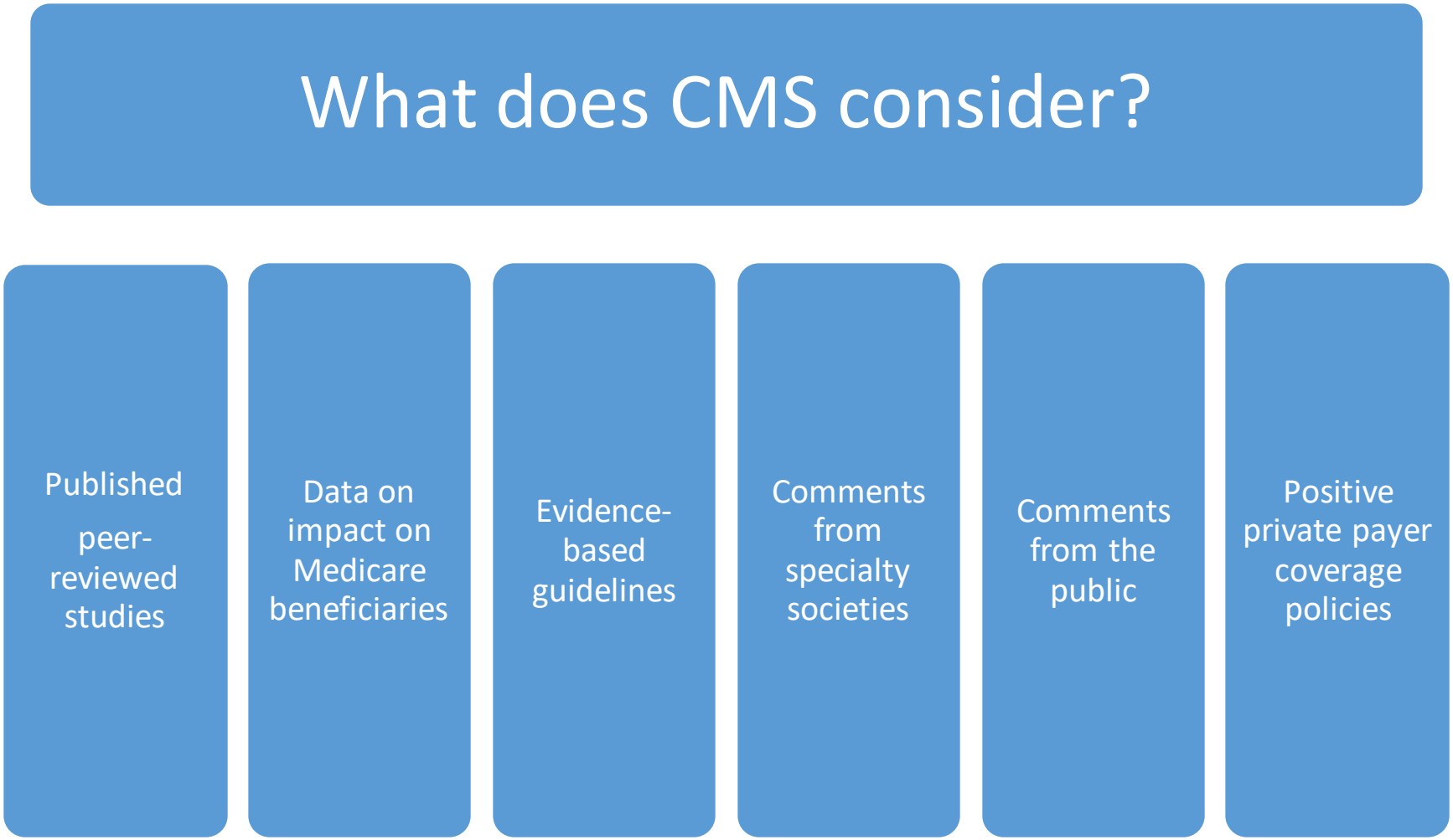
- Statutory and regulatory authority may specify coverage of preventive services
  - Flu shot
  - Mammogram
- Preventive services coverage through the National Coverage Determination (NCD) process if the service is a U.S. Preventive Services Task Force (USPSTF) recommended with grade A or B
  - Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)

Two Pathways for Coverage Decisions

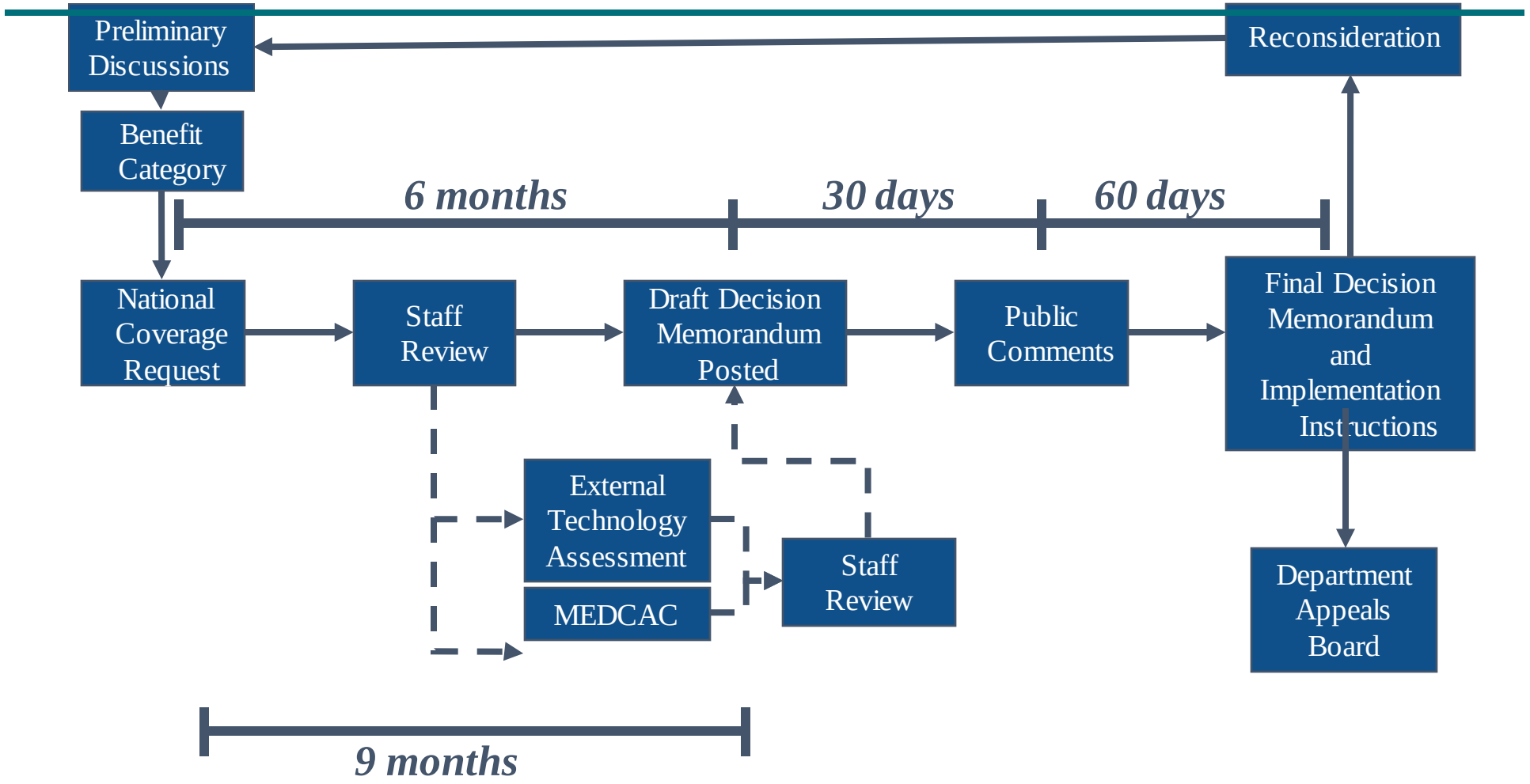
- **National Coverage Decisions (NCDs)**
  - Developed by CMS
    - Coverage & Analysis Group (CAG) a division of the Center for Clinical Standards & Quality (CCSQ)
  - Approximately 10% of covered items fall under an NCD
    - Currently 330 NCDs
    - Over 10,000 CPT codes
  - Coverage with Evidence Development (CEDs) are a subset of NCDs
    - Currently 21 CEDs (e.g., Leadless Pacemakers)
- **Local Coverage Decisions (LCDs)**
  - Developed by local Medicare Administrative Contractors (MACs)
  - Each MAC has approximately 100 LCDs

Note: Medicare does not make specific coverage decisions in all cases. Often, when a new technology is similar to an existing device that is currently covered by Medicare, the new device may be covered without any special process or determination by CMS.

CMS NCD Process



National Coverage Determination Process[1]



[1] 78 FR 48164-69

Removal of NCDs

- Rare but there is a process which CMS updated in FY 2021 PFS final rule which includes notice and comment[1]
- Circumstances considered for removal:
  - Allowing local contractors to make a coverage decision better serves the Medicare program and beneficiaries.
  - Technology is generally acknowledged to be obsolete and is no longer marketed.
  - Noncoverage NCD based on the experimental status of an item or service is no longer considered experimental
  - NCD has been superseded by subsequent Medicare policy
  - The national policy does not meet the definition of an "NCD" as defined in sections 1862(1) or 1869(f) of the Act
  - The benefit category determination is no longer consistent with a category in the Act.
  - Other factors including the general age of an NCD, changes in medical practice/standard of care, availability and quality of clinical evidence (could remove an CED).
- Example NCD 160.22 Ambulatory EEG Monitoring from 1984 removed in the FY 2023 PFS

[1] 86 FR 65241

NCD Example

Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (generated by request from private insurers)

Coverage with Evidence Development

CMS, as part of the NCD, may determine coverage of an item of service only in the context of a clinical study[1]

Statutory Basis: Sections 1862(a)(1)(A), 1862(a)(1)(E), and 1142 of the Act

- Sections 1862(a)(1)(A) and 1862(a)(1)(E) of the Act

  (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services-

  (1)(A) which, **except** for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member

  *****

  (E) In the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section

[1]Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development, https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27

Coverage with Evidence Development

Statutory Basis: Sections 1862(a)(1)(A), 1862(a)(1)(E), and 1142 of the Act

- Section 1142 of the Act describes the authority for AHRQ to conduct and support research on outcomes, effectiveness, and appropriateness of services to identify the most effective and appropriate means to prevent, diagnose, treat, and manage diseases, disorder, and other health conditions
- The coordination of AHRQ priorities under section 1142 with the needs and priorities of the Medicare program is accomplished through direct coordination. AHRQ reviews all CED NCDs established under Section 1862(a)(1)(E) of the Act

Principles Governing the Application of CED

- CED will occur within the coverage determination process which is open to public comment.
- CED will not be used when less restricted coverage is justified by the available evidence.
- CED will generally expand access to medical technologies for beneficiaries.
- CED will lead to the production of evidence complementary to existing medical evidence.
- CED will not duplicate or replace the FDA's authority in assuring the safety and efficacy of items and services.
- CED will not assume the NIH's role in fostering, managing, or prioritizing clinical trials.
- CED will be consistent with federal laws, regulations, and patient protections

Requirements for CED under Section 1862(a)(1)(E)

- The principal purpose to the study is to test whether the item or service meaningfully improves health outcomes of the affected beneficiaries who are represented by the enrolled subjects.
- The rationale for the study is well supported by available scientific and medical evidence.
- The results are not anticipated to unjustifiably duplicate existing knowledge.
- The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s).
- The study is sponsored by an organization or individual capable of completing it successfully.
- The study is in compliance with all applicable Federal regulations protecting human subjects.
- All aspects of the study are conducted according to appropriate standard of scientific integrity.

Requirements for CED under Section 1862(a)(1)(E)

- The study has a written protocol that adheres to Medicare requirements
- The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals.
- The clinical research studies and registries are registered on www.ClinicalTrials.gov
- The research study protocol specifies the method and timing of public release of all prespecified outcomes. The results must be made within 12 months of the study's primary completion date. Final results must be reported in a public manner.
- The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly underrepresented groups in clinical studies and a plan for retention of these populations in the study.
- The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations.

CED Example

Leadless Pacemakers (internally generated)

Ending CED

- CMS expects studies will produce evidence that will lead to revision of coverage policies (e.g., NCDs for oncologic uses of FDG PET).
- Sponsors should build interim analysis into their study design and communicate these results to CMS.
- A CED cycle is considered complete when CMS completes a reconsideration of the CED coverage decision and removes the requirement for study participation as a condition of coverage. The public may request reconsideration. The process is similar to the reconsideration for an NCD.

CED Factoids[1]

- 27 CED determinations were made from 2005 to 2022
  - 15% were diagnostic
  - 85% were interventional
- CEDs were from 8 therapeutic areas
  - Cardiovascular disease was 30% of the CEDs
- Duration of CED ranged from 1 to 16 years
- Only 4 CEDs were retired where the evidence appeared adequate
  - Carotid artery stenting, implantable cardioverter defibrillator for primary prevention of sudden cardiac death, MRI in patients with a cardiac implantable electronic device, and autologous blood-derived products for chronic nonhealing wounds
- Two CEDs led to coverage revocation and deferral to local coverage determination
  - Artificial hearts and home oxygen for cluster headaches

[1] Zeitler EP, Gilstrap LG, et al. Coverage with evidence development: where are we now?AJMC.2022,28(8):382-389.

AHRQ Report – Analysis of Requirements for Coverage with Evidence Development[1]

- Describes AHRQ's response to a request from CMS for recommendations about updates to the CED study design requirements.
- AHRQ's stated aim was to refine the study design requirements so that investigators are efficient in completing studies that contribute to an evidence base that can end the CED process when there is (1) sufficient evidence for a coverage NCD; (2) sufficient evidence for a non-coverage NCD; or (3) decision to defer to a MAC.
- Guiding Questions
  - What are the strengths and limitations of the current CED requirements?
  - What requirements are used by similar decision-making bodies
- Key Questions
  - What revisions to the CED requirements may best address the limitations while preserving the strengths?
  - How might the revised requirements be evaluated in the future?

[1] AHRQ Publication # 23-EHC003, November 2022

MEDCAC Meeting

- The MEDCAC panel examined and discussed the revisions of the requirements for clinical studies recommended by AHRQ's Evidence-Based Practice Program
  - The panel evaluated the proposed revisions to the CED requirements to ensure that CED studies are evaluated with consistent, feasible, transparent and methodologically rigorous requirements.
  - The panel will also advise CMS on whether the proposed revisions are appropriate to ensure that CED-approved studies will produce evidence that CMS can rely on to help determine whether a particular item or service is reasonable and necessary.
  - The meeting was not to discuss specific services or technologies
- MEDCAC voted on the AHRQ's recommendations
  - 0 is not important, 1 is important, 2 is essential
- Convened on February 13 and February 14, 2023
  - Meeting information is available on CMS website (https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEDCAC)

MEDCAC Voting

SPONSOR (1.7)

- The study is conducted by sponsor/investigators with the resources and skills to complete it successfully.

COMMUNICATION (No existing requirement) (1.9)

- A written plan describes the schedule for completion of key study milestones to ensure timely completion of the CED process.

GOVERNANCE (No existing requirement) (1.8)

- The protocol describes the information governance and data security process that have been established.

CONTEXT (2)

- The rationale for the study is supported by scientific evidence and study results are expected to fill the specified knowledge gap and provide evidence of net benefits
- Sponsors/investigators establish an evidentiary threshold for the primary outcome(s) to demonstrate clinically meaningful differences with sufficient precision.

MEDCAC Voting

OUTCOMES (No existing requirement) (1.9)

- The primary outcome(s) for the study are clinically meaningful and important

PROTOCOL (1.7)

- The study has a written protocol that adheres to Medicare requirements
- The clinical research studies are registered on www.ClinicalTrials.gov. Registries are registered in AHRQ.
- The CED study is registered with the Clinical Trials website and a complete protocol is delivered to CMS.

POPULATION (2)

- The study population reflects the demographics and clinical diversity among the Medicare beneficiaries who are the intended users of the intervention.

GENERALIZABLE (1.2)

- The study protocol explicitly discusses how results are or not expected to be generalizable to affected beneficiary subpopulations.
- Data for the study should come from beneficiaries in their usual site of care.

MEDCAC Voting

DATA QUALITY (No existing requirement) (2)

- The data are generated or selected with attention to completeness, accuracy, sufficiency of duration of observation to demonstrate durability of results, and sufficiency of sample size as required by the question

DATA USE (No existing requirement) (1.7)

- Sponsors/investigators provide information about the validity of the primary exposure and outcome measures, including use of secondary data

DESIGN (1.9)

- The study is methodologically appropriate and anticipated number of enrolled subjects is sufficient to answer the research question(s)
- The study design is selected to generate valid evidence safely and efficiently
- The sponsor/investigators minimize the impact of confounding and biases on interferences with rigorous design and appropriate statistical techniques

MEDCAC Voting

DESIGN SUBPOPULATIONS (1.5)

- The study protocol must explicitly discuss beneficiary subpopulations, particularly traditionally underrepresented groups in clinical studies.
- The sponsor/investigators describes plans for analyzing demographic subpopulations.

REPRODUCIBILITY (No existing requirement) (1.4)

- Sponsor/investigators using secondary data will demonstrate robustness of results by conducting alternative analyses and/or using supplementary data.

REPORTING (2)

- The research study protocol specifies the method and timing of public release of all specified outcomes, both positive and negative. Results must be made public within 12 months of the study's primary completion date.
- The study is submitted for peer review with the goal of publication

MEDCAC Voting

SHARING (No existing requirements) (1.9)

- The sponsor/investigators commit to sharing analytical output, methods, and analytic code with CMS or with a trusted third party. The study should comply with all applicable Federal laws.

LEGAL (1.2)

- The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals.
- The study is not designed to exclusively test toxicity, although it is acceptable to test a reduction in toxicity relative to a standard of care.

Coverage Issues for 2023

- Requirements for Coverage with Evidence
  - AHRQ report (No.23-EHC003) issued November 2022
  - CMS convened a panel of the MEDCAC February 13 and 14, 2023 to discuss this issue
  - Will CMS modify requirements?
- Transitional Coverage for Innovative Technology
  - Anticipate a proposed rule Spring 2023 which will define "innovative technology" and process for developing clinical evidence
  - CMS intends to develop a process for new devices that will promote access to emerging technologies and ensure beneficiaries have appropriate safe and effective treatment[1]

[1]Fleisher LA. Blum J.D. A Vision of Medicare Coverage for New and Emerging Technologies – A Consistent Process to Foster Innovation and Promote Value. JAMA Internal Medicine. 2022;182(12)1241-1242.

A Vision of Coverage for New and Emerging Technologies

- CMS is committed to making sure Medicare beneficiaries are able to access emerging technologies.
- A proposed rule will meet the following principles:
  - Manufacturers may enter the process on a voluntary basis. The process will be limited to medical devices that fall within the Medicare statute and that are relevant to Medicare beneficiaries.
  - CMS may conduct early evidence review (before FDA marketing authorization) and discuss with the manufacturer the best coverage pathway.
  - At the manufacturer's request, CMS may initiate the coverage process before FDA market authorization, which would require developing an additional evidence development plan and confirming there are appropriate safeguards and protections for Medicare beneficiaries.
  - If CMS determines that further evidence development is the best coverage pathway, the agency would explore how to reduce burden on manufacturers, clinicians, and patients while maintaining rigorous evidence requirements.

Questions/Comments

JD Lymon GROUP

“Coverage” Opportunities for Novel Technologies

April 19, 2023

Agenda

- Introductions
- Incremental Medicare Facility Payment Mechanisms
- New Technology Add-On Payment (NTAP)
- Transitional Pass-Through Payment Status (TPT)
- Substantial Clinical Improvement (SCI)
- Summary

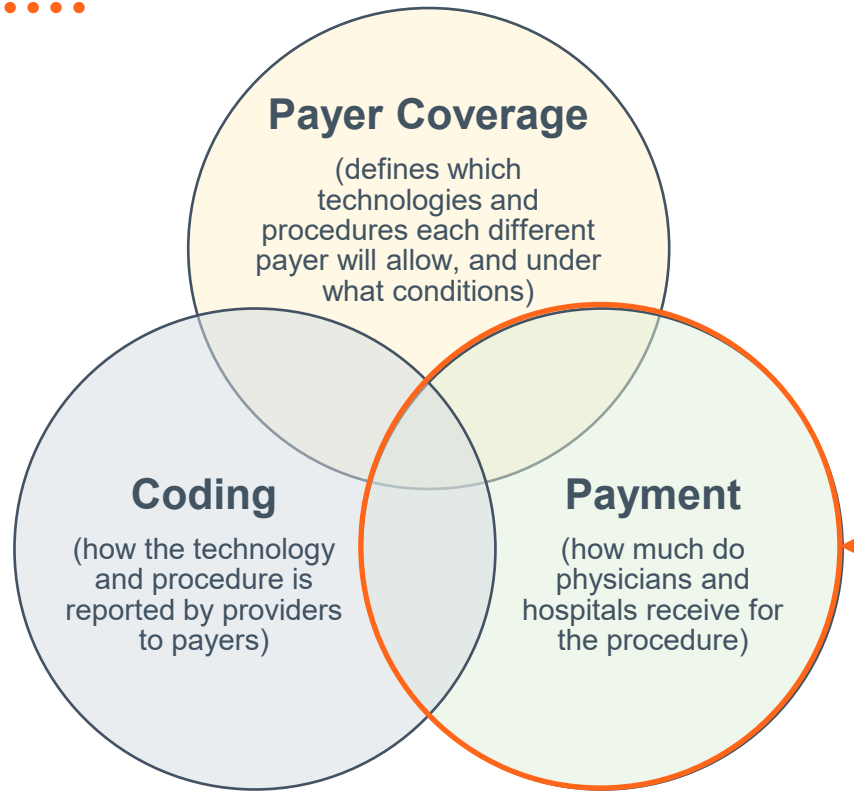
JD Lymon Group, LLC

- We are a Minneapolis, Minnesota based market access consulting firm
- We provide strategic market access consulting solutions that address the complex relationships between evidence, coding, coverage policy, payment and health care decision makers
- Mark Domyahn
  - 25+ year career entirely in the health care industry, with the vast majority focused on medical technology, provider reimbursement and health economics.
  - Previous companies include Medtronic, Restore Medical, CardioMEMS, Zimmer and St. Jude Medical
  - Prior to joining the JD Lymon Group, Mark founded Pursuance Consulting, a reimbursement and health economics consulting practice.

mdomyahn@jdlymon.com

Incremental Medicare Facility Payment Mechanisms

U.S. Reimbursement



What we will be discussing today

Incremental Medicare Facility Payment Mechanisms

- Hospital payment rates (i.e., MS-DRGs and APCs) are based on historical claims data from two years ago
  - Cost of new technology cannot be included in the current payment rates
- CMS mechanisms to address facility payment for “new” technology:
  - **Hospital Inpatient – New Technology Add-On Payment (NTAP)**
  - **Hospital Outpatient – Transitional Pass-Through (TPT)**
  - Hospital Outpatient – New Technology APC
  - ESRD facilities – TPNIES*
- Purpose is for CMS to collect sufficient claims data to incorporate the new technology into hospital MS-DRG / APC payment rates
  - Applies only to Medicare Fee-for-Service patients
- Can secure NTAP and TPT only after FDA approval is received

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

Frequent Statements on NTAP and TPT

Frequent Statement	My Response	My Rationale
NTAP / TPT provide a fixed payment amount		
Hospitals understand how NTAP and TPT are calculated		
Other payers will also pay more because of NTAP and TPT		
Once NTAP/TPT expires, CMS will give me my own DRG/APC		
NTAP and TPT only apply to the applicant's technology		
BDD isn't that big a deal because MCIT went away		

New Technology Add-On Payment (NTAP)

NTAP Criteria and Considerations

	Criteria	Considerations
Requirements	Must be "New" compared to existing technology • FDA approval date within NTAP window • Not substantially similar to existing technologies	• Apply for NTAP based on expected FDA approval • Substantial similarity based on 3 things compared to existing technologies: 1) Mechanism of Action; 2) DRG assignment; 3) Patient population treated
	Meet a MS-DRG charge threshold based on total case charges	• Does not include the cost of capital • Utilize average technology cost per discharge
	Provide a SCI over existing therapies	Discussed later in presentation
Timeline	Annual – effective October 1	• Typical to apply for NTAP prior to FDA approval • Timing dependent on a July 1 FDA approval date • Apply for NTAP by **October 17, 2022,** if FDA approval can occur prior to **July 1, 2023**
Duration	2 or 3 years	• Based typically on when FDA approval occurs • Approval between **April 1-June 30** begets 3 years
Administration	ICD-10-PCS codes in conjunction with diagnosis codes if necessary	• Requires distinct PCS codes to identify technology • Engage CMS to create new codes when necessary
Incremental Payment	65% of incremental cost of discharge over hospital's DRG payment, capped at 65% of the cost of the new technology	• Hospital discharge specific calculation • In theory, the hospital will lose money on every case

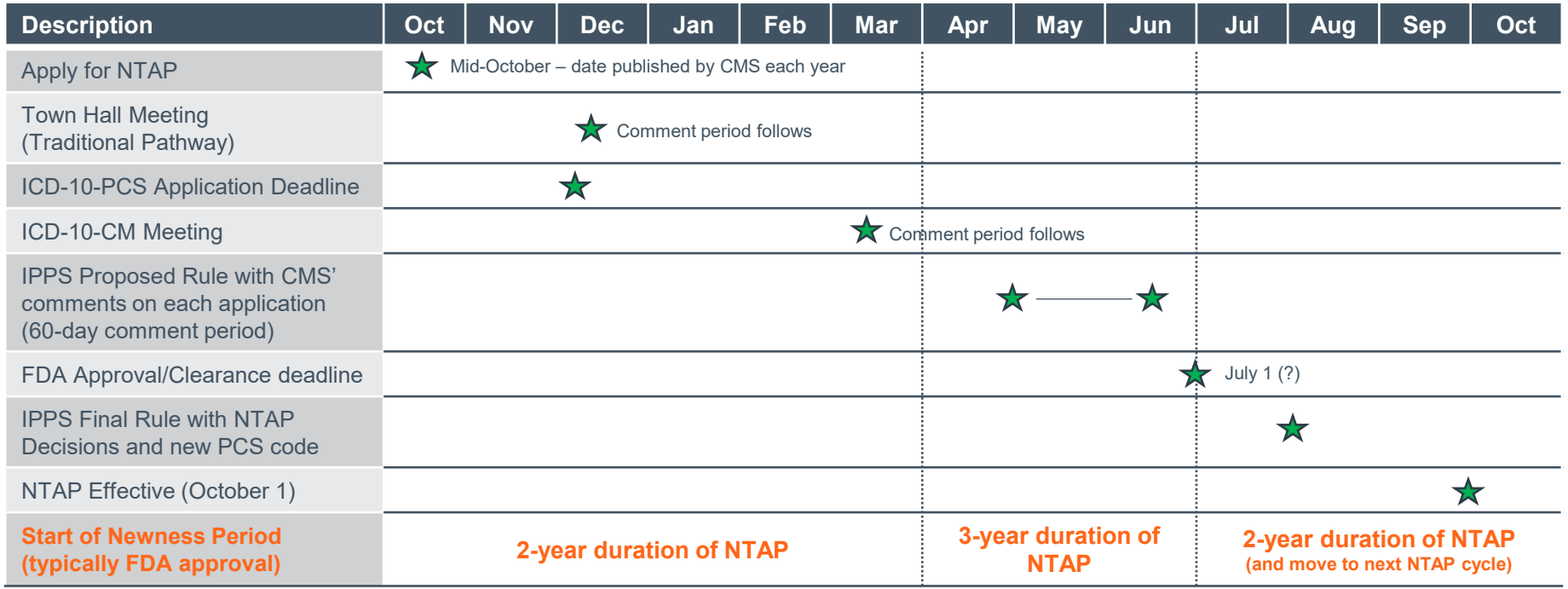
*Criteria impacted for devices with Breakthrough Device Designation (BDD)

NTAP Payment Calculation

NTAP payment amount is calculated on each claim, and can vary

Illustrative Hospital Level NTAP Calculation	Hospital A	Hospital B	Hospital C
Total Charges of the Entire Hospital Discharge	$90,000	$105,000	$102,000
Hospital-Specific Operating Cost to Charge Ratio	x 0.2065	x 0.2609	x 0.3501
Hospital-Specific Reported Cost of the Hospital Discharge	$18,585	$27,395	$35,710
Hospital Specific MS-DRG 264 Payment Amount	- $21,100	- $22,750	- $24,400
Difference	$(2,515)	$4,645	$11,310
65% of the Difference	N/A	$3,019	$7,352
NTAP Cap: Cost of New Technology ($10,000) x 65%		$6,500	
Incremental NTAP Payment – Lesser of 65% Difference or the Cap	**$0**	**$3,019**	**$6,500**
Total Payment – **MS-DRG 264 + NTAP Payment**	**$21,100**	**$25,769**	**$30,900**

NTAP Timeline



Proposed FY 2024 – Continuing NTAPs

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2023	Coding Used to Identify Cases Eligible for NTAP
1	*Intercept® (PRCFC)*	*05/05/2021*	*10/1/2021*	*5/05/2024*	86 FR 45149 through 45150 86 FR 67875 87 FR 48913	$2,535.00	30233D1 or 30243D1 in combination with one of the following D62, D65, D68.2, D68.4 or D68.9
2	*Rybrevant™*	*05/21/2021*	*10/1/2021*	*05/21/2024*	86 FR 44988 through 44996 87 FR 48913	$6,405.89	XW033B7 or XW043B7
3	*StrataGraft®*	*06/15/2021*	*10/1/2021*	*06/15/2024*	86 FR 45079 through 45090 87 FR 48913	$44,200.00	XHRPXF7
4	*aprevo® Intervertebral Body Fusion Device*	*6/30/2021 (TLIF)*	*10/1/2021*	*6/30/2024 (TLIF)*	86 FR 45127 through 45133 86 FR 67874 through 67876 87 FR 48913	$40,950.00	XRGA0R7 or XRGA3R7 orXRGA4R7 or XRGB0R7 or XRGB3R7 or XRGB4R7 or XRGC0R7 or XRGC3R7 or XRGC4R7 or XRGD0R7 or XRGD3R7 or XRGD4R7
5	*Hemolung Respiratory Assist System (RAS)*	*11/15/2021 (other)*	*10/1/2022*	*11/15/2024 (other)*	87 FR 48937 through 48948	$6,500.00	5A0920Z without U07.1*
6	*Livtencity™*	*12/2/2021*	*10/1/2022*	*12/2/2024*	87 FR 48948 through 48954	$32,500.00	XW0DX38 or XW0G738 or XW0H738
7	*Thoraflex Hybrid Device*	*04/19/2022*	*10/1/2022*	*04/19/2025*	87 FR 48974 through 48975	$22,750.00	X2RX0N7 in combination with X2VW0N7
8	*ViviStim*	*04/29/2022*	*10/1/2022*	*04/29/2025*	87 FR 48975 through 48977	$23,400.00	X0HQ3R8
9	*GORE TAG Thoracic Branch Endoprosthesis*	*05/13/2022*	*10/1/2022*	*05/13/2025*	87 FR 48966 through 48969	$27,807.00	02VW3DZ in combination with 02VX3EZ
10	*Cerament® G*	*05/17/2022*	*10/1/2022*	*05/17/2025*	87 FR 48961 through 48966	$4,918.55	XW0V0P7
11	*iFuse Bedrock Granite Implant System*	*05/26/2022*	*10/1/2022*	*05/26/2025*	87 FR 48969 through 48974	$9,828.00	XNH6058 or XNH6358 or XNH7058 or XNH7358 or XRGE058 or XRGE358 or XRGF058 or XRGF358

*As discussed in the following section, we are proposing to discontinue new technology add-on payments for COVID-19 Hemolung RAS cases.

Table II.P.-01, CMS-1785-P

Proposed FY 2024 – Discontinued NTAPs

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations
1	TECARTUS®	7/4/2020	10/1/2021	7/4/2023	86 FR 45090 through 45104 87 FR 48913
2	VEKLURY®*	7/1/2020*	10/1/2021	7/1/2023*	86 FR 45104 through 45116 87 FR 48909 through 48914
3	Zepzelca™	6/15/2020	10/1/2021	6/15/2023	86 FR 45116 through 45126 87 FR 48912 through 48913
4	aScope® Duodeno	7/17/2020	10/1/2021	7/17/2023	86 FR 45133 through 45135 87 FR 48912 through 48916
5	Caption Guidance™	9/15/2020	10/1/2021	9/15/2023	86 FR 45135 through 45138 87 FR 48911 through 48913
6	aprevo® Intervertebral Body Fusion Device	12/3/2020 (ALIF and LLIF)	10/1/2021	12/3/2023 (ALIF and LLIF)	86 FR 45127 through 45133 86 FR 67874 through 67876 87 FR 48913
7	Cosela™	2/12/2021	10/1/2021	2/12/2024	86 FR 45008 through 45017 87 FR 48912 through 48913
8	ShockWave C2 Intravascular Lithotripsy (IVL) System	2/12/2021	10/1/2021	2/12/2024	86 FR 45151 through 45153 87 FR 48913
9	ABECMA®	3/26/2021	10/1/2021	3/26/2024	86 FR 45028 through 45035 87 FR 48911 through 48925
10	Harmony™ Transcatheter Pulmonary Valve (TPV) System	03/26/2021	10/1/2021	3/26/2024	86 FR 45146 through 45149 87 FR 48913
11	Recarbrio™ (HABP/VABP)	6/4/2020	10/1/2021	6/4/2023	86 FR 45157 through 45158 86 FR 67874 87 FR 48914
12	Fetroja® (HABP/VABP)	9/25/2020	10/1/2021	9/25/2023	86 FR 45156 through 45157 86 FR 67876 87 FR 48913
13	DARZALEX FASPRO®	01/15/2021	10/1/2022	01/15/2024	87 FR 48925 through 48937
14	CARVYKTI™	03/26/2021**	10/1/2022	03/26/2024	87 FR 48920 through 48925
15	Hemolung Respiratory Assist System (RAS)	04/22/2020 (COVID-19)	10/1/2022	04/22/2023 (COVID-19)	87 FR 48937 through 48948

*See discussion in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48909 through 48914).
** As discussed in the FY 2023 IPPS/LTCH PPS final rule, because we determined that CARVYKTI™ is substantially similar to ABECMA®, we consider the beginning of the newness period for CARVYKTI™ to be March 26, 2021, which is the date that ABECMA® received FDA marketing authorization (87 FR 48925).

Table II.P.-02, CMS-1785-P

FY 2024 Proposed Hospital Inpatient Rule

- For the first time, the FY 2024 NTAP publications are available at https://mearis.cms.gov/public/publications/ntap
- CMS received 54 NTAP applications (15 applicants withdrew)
  - Traditional Pathway – 19 applications discussed in the proposed rule
  - Alternative Pathway – 20 applications discussed in the proposed rule
  - Any interested stakeholder can provide comments to CMS on any of the applications
- CMS has proposed two policy changes given the growth in the number of NTAP applications (both are negative and should be opposed)
  - Moving the FDA deadline from July 1 to May 1
  - A full FDA submission must be active prior to applying for NTAP
  - **CMS will accept comments by June 9 at www.regulations.gov**

Transitional Pass-Through Payment Status (TPT)

Initial Transitional Pass-Through Qualifications

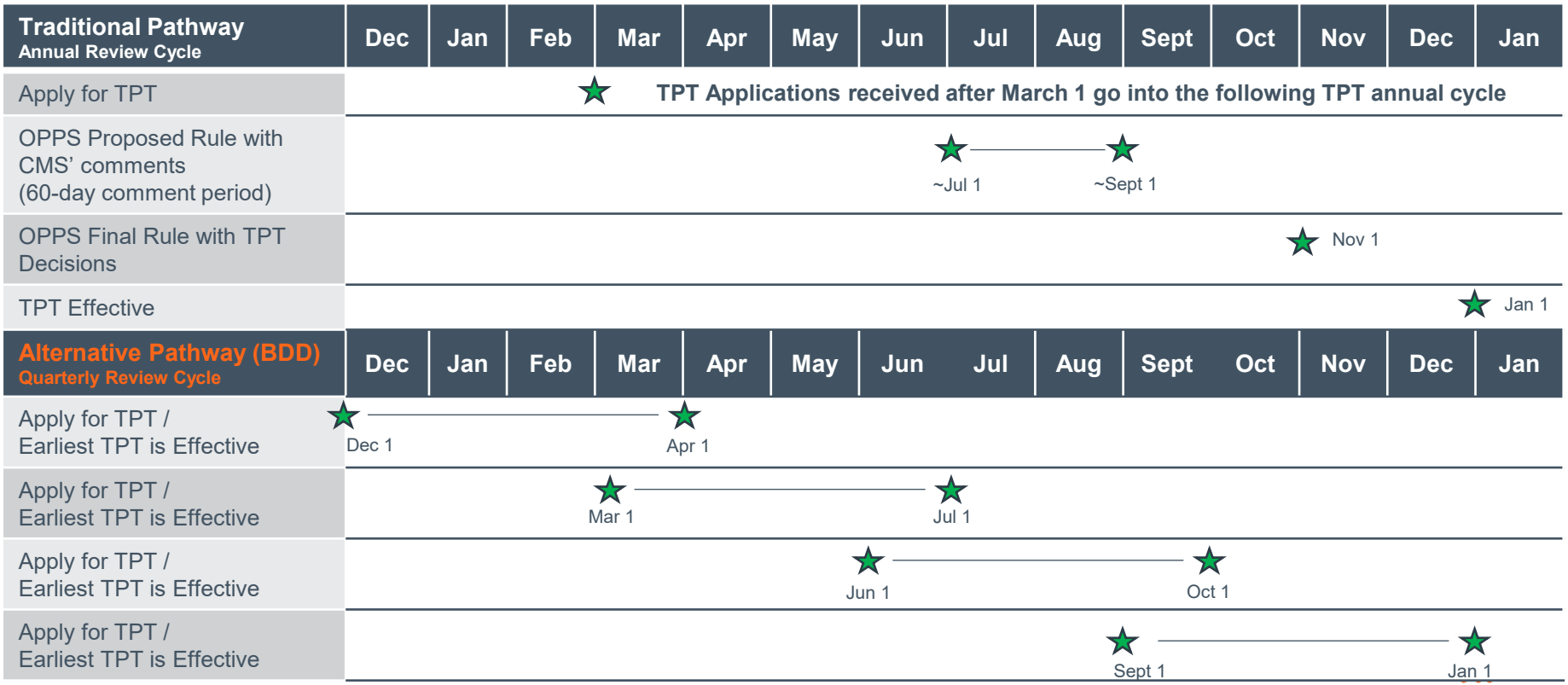
- Must have FDA approval or clearance
- Device must:
  - Be an integral part of the service furnished, and
  - Be used in one patient only, and
  - Come in contact with human skin, and
  - Be surgically implanted or inserted, or applied in or on a wound/other skin lesion
- Device is not any of the following
  - Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets
  - A material or supply furnished incident to a service (e.g.,, a suture, customized surgical kit, scalpel, or clip, other than radiological site marker)

TPT Criteria and Considerations

	Criteria	Considerations
Requirements	Must be “New” compared to existing technology • FDA approval date within TPT window • Cannot be described by a previous/current device category	• Must apply within three years of FDA approval • Interpretation of what is / is not included in device categories is at the discretion of CMS
	Meet three cost criteria on cost of new technology	• Cost of technology is expected average sales price net of rebates, discounts, etc. (i.e., not list price) • See next slide
	Provide a SCI over existing therapies	Discussed later in presentation
Timeline	• Annual – effective January 1 • Quarterly – based on application submission	• Timing of application is critical • Traditional pathway – March 1 is a critical date • Alternative pathway – more flexibility for company when they prefer TPT to become effective
Administration	CMS creates a new device category (C-Code)	No additional effort required
Incremental Payment	100% of reported cost of device less device related portion of procedure (+ APC)	• Hospital specific calculation • In theory, the hospital should not lose money • TPT payment for ASCs is administered by the MACs

*Criteria impacted for devices with Breakthrough Device Designation (BDD)

TPT Timeline



TPT Cost Criteria

- Three cost criteria must be met to qualify for TPT
  - These criteria must be met at time of the application is submitted
  - Key issues include APC assignment and DRP at the procedure level

Criteria	Cochlear Implant		Thumb Fusion	
CPT Code for Procedure	69930		26841	
2023 APC Assignment	**5166**		**5114**	
2023 APC Payment*	$33,337		$6,615	
2023 Device Related Portion (DRP)* of CPT Code	$26,636 (80%)		$1,459 (22%)	
Expected Average Cost of Device (ACD)	**TBD**		**TBD**	
Three Criteria (Actual must be > Threshold)**	**Threshold**	**Required**	**Threshold**	**Required**
ACD Cost > 25% of APC Payment	$8,334	$8,335	$1,654	$1,680
ACD Cost > 125% of DRP	$33,295	**$33,296**	$1,824	$1,825
(Difference between ACD and DRP) > 10% of APC payment	$3,334	$29,970	$662	**$2,122**

Hospital Outpatient TPT Payment Calculation

- TPT is an incremental payment calculated at the hospital level, and is dependent on two hospital-specific factors:
  - Specific charges for the new technology
  - Implantable devices charge to patients cost to charge ratio (CCR)

Description	New Thumb Fusion Technology		
Hospital charges for New Technology	**$7,800**	**$10,000**	**$13,500**
Hospital specific CCR – Implantable Devices Charged to Patients	x 0.2564	x 0.2951	x 0.3699
Reported Cost of New Technology (e.g., ASP is $3,000)	$2,000	$2,951	$4,994
Device Related Portion for the CPT Code	- $1,459	- $1,459	- $1,459
Transitional Pass-Through Payment (incremental)	**$541**	**$1,492**	**$3,535**
APC 5114 Payment	+ $6,615	+ $6,615	+ $6,615
Total Payment – APC 5114 + TPT	**$7,156**	**$8,107**	**$10,150**

Key Considerations for TPT

- Are there existing device categories that describe your device?
  - CY 2022 – Eluvia drug-eluting stent
  - CY 2023 – EVOKE and ViviStim
- Does your technology include a single device or multiple devices?
  - This can impact the three cost criteria, as the cost of the technology is compared against the entire device related portion (DRP of a procedure)
- Cost criteria includes components eligible for TPT (i.e., no capital)
- If you have Breakthrough Designation, what is the optimal time period to leverage TPT?
  - Quarterly approvals available for TPT, which means quarterly expiration of TPT (mind the gap)
- As you evaluate pricing, where do you want to be when TPT expires?
  - Keep the end in mind

CY 2023 TPT Decisions

- Eight CY 2023 applications discussed in the Final Rule (CMS-1772-FC)
  - aprevo – effective October 1, 2022 and received $0 offset
  - ViviStim – able to address device category issues
  - EVOKE – able to demonstrate SCI in an established therapy area
  - Uretero 1 – able to demonstrate SCI based on single-patient use device
  - Brain Scope TBI – did not meet device eligibility requirements
  - Smart Clip – did not meet newness criteria based on FDA clearance date
  - NavSlim and NavPencil – unable to demonstrate SCI
  - Pathfinder Endoscope – unable to demonstrate SCI
- Post TPT – effective January 1, 2023
  - Impulse Dynamics (CPT code 0408T) – reassigned to higher paying clinical APC
  - Respicardia (CPT code 0424T) – reassigned to a New Technology APC

Substantial Clinical Improvement (SCI)

Substantial Clinical Improvement

- SCI is similarly defined for NTAP and TPT
  - CMS determines that a device to be included in the category will **substantially improve** the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part **compared to at least one other currently available and appropriate treatment or diagnostic test** (i.e., considered a standard of care, currently in use and utilized by the **Medicare population**)
  - Whether a candidate device provides substantial clinical improvement is evaluated by one or more of the following
    a) The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments
    b) The device can diagnose a medical condition currently undetectable, **or** diagnoses a medical condition earlier than is currently possible **and** an earlier diagnosis results in better outcomes. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf
Bolding added for emphasis by JD Lymon

Substantial Clinical Improvement

c) Use of the device significantly improves **clinical outcomes** for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:

- Reduced mortality rate with use of the device
- Reduced rate of device-related complications
- Decreased rate of subsequent diagnostic or therapeutic interventions (e.g., due to reduced rate of recurrence of the disease process)
- Decreased number of future hospitalizations or physician visits
- More rapid beneficial resolution of the disease process treated because of the use of the device
- Decreased pain, bleeding, or other quantifiable symptom
- Reduced recovery time

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf
Bolding added for emphasis by JD Lymon

Substantial Clinical Improvement

- Recent Changes
  - 2023 NTAP Application now includes a fourth potential criterion:

    *"The **totality of the circumstances** otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries."*
  - Both applications now require a tabular account of SCI claims
    - Claim
    - Supporting evidence reference
    - Study type & comparator
    - Page number and paragraph of cited study
    - Summary of information including sample sizes informing the claim

Select SCI Sentiments of Note

- Correlation is not causation
- Cost-effectiveness is not a relevant SCI argument
- Lack of replication of RCT results often cited as evidence shortcoming
- Lack of comparison to more than one available treatment often cited as evidence shortcoming
- Small sample sizes
- Imbalanced treatment groups
- Minor adverse events not necessarily “clinical outcomes”
- Questions of observed treatment effect due to device or trial design

Recommendations

- The definition of SCI is broad, but CMS reviews tend to assess a few key elements
- In the absence of BDD, if an eventual SCI argument is planned, consider the following:
  - Can you randomize against an accepted standard of care?
  - Will it be straightforward to fill out the required SCI table? (i.e., cite reference page and paragraph showing SCI claim with supporting sample sizes)
  - Can you power your study to demonstrate superiority in a clinical endpoint?

Summary

Frequent Statements on NTAP and TPT

Frequent Statement	My Response	My Rationale
NTAP / TPT provide a fixed payment amount	False	Both NTAP and TPT are hospital level calculations
Hospitals understand how NTAP and TPT are calculated	False	Hospital education is critical to fully maximize the opportunity NTAP and TPT represent
Other payers will also pay more because of NTAP and TPT	Maybe?	NTAP and TPT only apply to Medicare fee-for-service patients – many other payers (including Medicare Advantage) negotiate payment rates
Once NTAP/TPT expires, CMS will give me my own DRG/APC	Maybe, But Certainly Not Guaranteed	• Securing new MS-DRGs or APCs is difficult • Reclassification to an existing DRG/APC may be more realistic
NTAP and TPT only apply to the applicant's technology	False	CMS is clear that NTAP and TPT are for "categories," and it is up to the hospital to determine the most appropriate coding
BDD isn't that big a deal because MCIT went away	False	BDD increases the probability of securing NTAP and TPT significantly

Summary

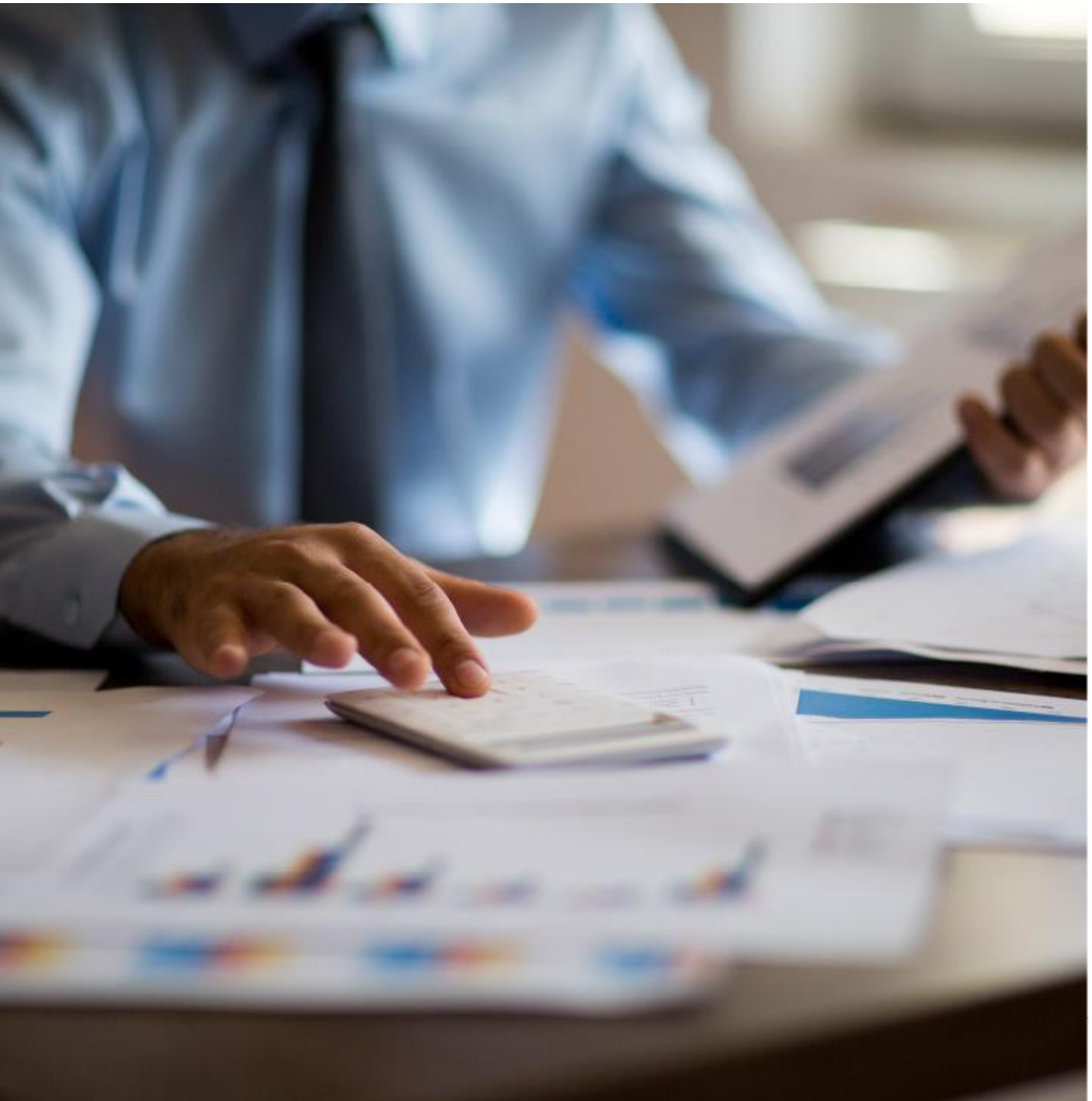
- NTAP and TPT can help accelerate market adoption by providing incremental payment
- Important to understand the payer mix of your technology – the more Medicare, the more advantageous NTAP/TPT are
- If possible, secure Breakthrough Device Designation
- Think about NTAP/TPT, as well as the “end game” when determining the price of your technology
- Once NTAP/TPT is secured, do not underestimate the level of hospital engagement that is required
  - CMS doesn’t collect invoices – they collect hospital charges and claims
  - Educate hospitals on how Medicare calculates the incremental payment levels
  - Ongoing monitoring to ensure hospitals are reporting costs appropriately

Thank You

Contact Information:

Mark Domyahn – mdomyahn@jdlymon.com

www.jdlymon.com



HMA

Overview of Alternative Payment Models

PRESENTED BY:
Amy Bassano,

Managing Director, Medicare

April 19, 2023

WHY VALUE-BASED PAYMENT?

The current system is not working
Fee-for-service (FFS) payment model incentivizes overutilization
Fee schedules reward treatment over prevention
Fragmented care delivery system
Inefficient/nonexistent data sharing
Lack of accountability for patient outcomes
Providers equipped to deliver care to individuals, not proactively manage populations
Insufficient resources for intensive care management of high-cost patients
Social determinants of health largely ignored by medical system

WHAT IS VALUE-BASED PAYMENT, EXACTLY?

Value-based payment (VBP) is a broad term that refers to payment innovations designed to incentivize and enable care delivery strategies that reduce overall costs while improving quality outcomes.

An alternative payment model (APM) is a specific application of VBP. APMs alter the way that health care services are paid for by utilizing alternative payment mechanisms (i.e., not just FFS) to incentivize high-quality, cost-efficient care.

$$\text{VALUE} = \frac{\text{OUTCOMES}}{\text{COSTS}}$$

Other labels used to describe various applications of value-oriented principles include:

- Value-Based Care
- Value-Based Contracting
- Value-Based Purchasing
- Value-Based Reimbursement
- Alternative Payment Models
- Accountable Care
- Outcomes-Based Pricing
- Cost, Quality, Outcomes (CQO)

CMS INNOVATION CENTER AND ALTERNATIVE PAYMENT MODELS

The Affordable Care Act created the Center for Medicare and Medicaid Innovation (CMMI) to test alternative payment models.

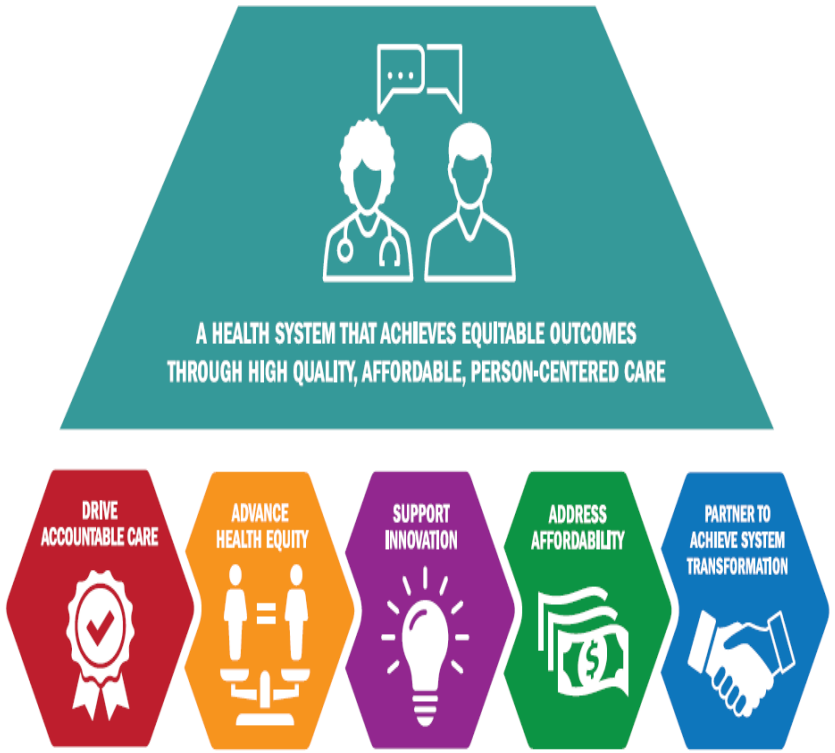
- Broad authority to test Medicare and Medicaid models. Can waive certain provisions of law to implement models.
  - If models are determined to be successful, the Secretary has authority to expand the model.
- Model can be voluntary or mandatory. Must be evaluated.
- More than 50 models tested. Most are Medicare payment focused. Fewer Medicaid models due to flexibility authorities.
- CMMI portfolio has focused on certain model approaches
  - Accountable Care Organizations/population health (Pioneer, Next Gen ACO, ACO REACH)
  - Bundled or episodic payments (BPCI, BPCIA, CJR)
  - Primary Care improvement (CPC, CPC+, PCF)
  - State Based initiatives (Maryland Total Cost of Care, Vermont All Payer, Pennsylvania Rural Health Model)
  - Health Conditions – ESRD (CEC, KCC, ETC), oncology (OCM)
- The Quality Payment Program incentivizes physicians to participate in certain CMMI models.

CMMI RESULTS AND LESSONS LEARNED

- As of March 2023, 4 models have met the expansion criteria
  - Pioneer ACO
  - Diabetes Prevention Program
  - Home Health Value Based Purchasing
  - Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT)
- Others such as the Maryland All-Payer Model achieved savings but CMMI developed a successor model (Maryland Total Cost of Care) to test concept more broadly in Maryland
- It is difficult to achieve savings in models especially when CMS need to take in to account additional costs of infrastructure, incentive or other new payments provided in the course of the model.
- Stakeholder concerns about the number of models, overlap between models, types of models (voluntary vs mandatory) and opportunities for certain types of providers to participate in models.

CMMI STRATEGY REFRESH

Building on lessons learned to date, CMMI looks to set the stage for future model tests and engagement with other payers and partners to support a system wide movement to value based payment



+ Drive accountable care that results in all Medicare enrollees and "the vast majority of Medicaid beneficiaries [will be] in a care relationship with accountability for quality and total cost of care by 2030."
+ Embed health equity in all models through mandatory reporting of demographic and, as appropriate, social determinants of health data, and including underserved populations and safety net providers in new models.
+ Support innovation by strengthening patient engagement and person-centered measures across all models.
+ Facilitate approaches and specific targets that address price and affordability for high-value care, including new approaches to cost-sharing and drug prices.
+ Pursue more collaborative and ongoing partnerships with a broader group of stakeholders to improve quality, achieve equitable outcomes and reduce health care costs, and allow for multi-payer alignment in new models by 2030.

COMPREHENSIVE CARE FOR JOINT REPLACEMENT (CJR)

- CMMI's first mandatory model. Changes payment for hips and knee replacements. Highest volume procedures for Medicare beneficiaries
- Originally implemented in 2016. Scheduled to run through 2024
- Approx. 324 hospitals in 34 Metropolitan Statistical Areas
- Design based on voluntary Bundled Payment for Care Improvement (BPCI) -
  - 90-day episode that begins with participating hospital admit,
  - Hospital accountable for total cost of care
  - Hospital must coordinate for post-acute care.
- Model has been modified since initial implementation
  - Geographic areas scaled back
  - Now accounts for outpatient procedures
  - Modified benchmarks to reflect updated costs of care
- Model has achieved non-statistically significant savings, fundamentally changed way post-acute care is delivered for these patients, other improvements in quality
- Will it be expanded?

ACO REALIZING EQUITY, ACCESS, AND COMMUNITY HEALTH (REACH)

- Most recent generation of CMMI ACO models
- Builds off of Direct Contracting Model
- Implemented in 2023. 132 ACO participating in Standard, New Entrant and High Needs tracks
- ACO takes on annual responsibility for beneficiaries assigned to them through claims based or voluntary attribution.
- Two levels of risk – Global or Professional
- Multiple payment approaches – capitation, advance pay, etc
- Multiple beneficiary enhancements to support delivery redesign, flexibility and health equity
- ACOs earn savings if successfully reduce spending below target.
- Promoting health equity and addressing health care disparities for underserved communities key parts of model and are reflected in payment and quality approaches
- Oversight, transparency and provider engagement also key

ONCOLOGY CARE MODEL (OCM)

- Six-year model (2016-2022) to test innovative payment strategies that promote high-quality and high-value cancer care
- Real-time monthly payments (MEOS) that pay for enhanced services for beneficiaries combined with usual Medicare FFS payments and the potential for a retrospective performance-based payment based on quality and savings
- Episode-based Payment model targets chemotherapy and related care during a 6- month period that begins with receipt of chemotherapy treatment
- Emphasizes practice transformation
- First model to address Part D costs when looking at total cost of care
- Multi-payer model
  - Includes Medicare fee-for-service and other payers working in tandem to leverage the opportunity to transform care for oncology patients across the practice's population
- 127 practices participated

ONCOLOGY CARE MODEL – NOVEL THERAPIES ADJUSTMENT

- Potential adjustment based on the percentage of each practice's average episode expenditures for novel therapies compared to the percentage for practices that are not part of OCM
- Includes oncology drugs that received FDA approval after 12/31/14 –
- Use of the novel therapy must be consistent with the FDA-approved indications for inclusion in the adjustment
- Oncology drugs are considered "new" for 2 years from FDA approval for that specific indication
- The novel therapies adjustment may lead to a higher benchmark only (i.e., it will never lower a benchmark)

ENHANCING ONCOLOGY MODEL

- Successor model to OCM and builds off lessons learned and experience of CMS and providers
- More limited focus than OCM – Only beneficiaries receiving systemic chemotherapy (not hormonal therapy only) for seven cancer types: breast cancer, chronic leukemia, small intestine/colorectal cancer, lung cancer, lymphoma, multiple myeloma, and prostate cancer.
- Five-year model scheduled to begin July 1, 2023
- Monthly Enhanced Oncology Services (MEOS) payment ($70) for Enhanced Services provided to eligible beneficiaries. The MEOS payment will be higher ($30) for beneficiaries dually eligible for Medicare and Medicaid. Lower monthly amount from OCM.
- Downside risk required
- Required to implement participant redesign activities similar to OCM
- Episodes that include CAR-T will be excluded from the model due to high costs
- Novel therapy adjustment similar to OCM
- Explicit Health Equity Strategy

CMMI HAS CONSIDERED USING ITS AUTHORITY IN THE DRUG PRICING AREA MULTIPLE TIMES

- Mandatory Part B drug model 2016 Certain Part B drugs model would have paid ASP plus 2.5 percent and a flat fee. Also considered using other value-based purchasing tools – NOT IMPLEMENTED
- Most Favored Nation (MFN) Model 2020 – Certain Part B drugs, model would have paid no more than the lowest price that drug manufacturers receive in other similar countries. Providers paid a flat add-on amount for each dose of an MFN drug, instead of a percentage of each drug's cost – NOT IMPLEMENTED
- Part D Payment Modernization Model- 2020, CANCELLED in 2021
  - In 2020, allowed Participating Part D plans to take increased risk for CMS's federal reinsurance subsidy (80 percent of catastrophic and in turn plans could earn performance-based payments or would owe CMS depending on how well they managed the risk. send payments to CMS based on spending.
  - In 2021, other flexibilities including
    - Part D rewards and incentives programs;
    - Medication Therapy Management+ (MTM+) Programs;
    - Flexibility to lower costs for beneficiaries through limited initial days' supply and cost-sharing smoothing;
    - Cutting or removing cost-sharing on generic drugs and biosimilars for Low-Income Subsidy (LIS) beneficiaries (allowed for basic and enhanced alternative plan types); or
    - Plan timeliness for standard initial coverage determinations.

INFLATION REDUCTION ACT RELATED INITIATIVES

- In October 2022, President Biden issued an Executive Order (EO) for CMMI to develop a report within 90 days to outline any models it could test that would address drug pricing issues and to include a timeline for testing any of these models.
- On February 14, 2022, CMS released a report responding to the EO and announced the agency will explore three prescription drug payment models run by CMMI.
- The model concepts focus on the following:
  - Medicare High-Value Drug List
  - Cell and Gene Therapy (CGT) Access
  - Accelerating Clinical Evidence - mandatory model
- The report identifies additional areas for CMS to research, including:
  - Opportunities to encourage price transparency for prescription drugs
  - Options to improve biosimilar adoption
  - Medicare fee-for-service options to support CGT access and affordability

QUESTIONS/DISCUSSION

THANK YOU!

CONTACT ME:

AMY BASSANO
Managing Director
Health Management Associates

2000 M St NW Suite 700
Washington, DC 20036
phone |202-601-7748
abassano@healthmanagement.com

www.healthmanagement.com

HEALTH ECONOMICS & REIMBURSEMENT

ADVAMED MEDICAL DEVICE REIMBURSEMENT 101 WORKSHOP

The World Outside CMS

19 | April | 23

Sara Davis
Sr. Director, Global Operations, Market Access, and Customer Education

A Little About Me

25+ years in the medical device space

- 10 years Marketing Focus
  - Experience with start-up and established companies
  - Learned ‘how to tell a story’
- 17 years Health Economics & Reimbursement Focus
  - Bases Covered: CMS submissions, coding applications, customer assistance, payer work
  - Payer Focus: Commercial and Medicare
  - Start-up world with new products
    - » Coverage: non-existent
  - Established world with a mix of product life-stages
    - » Coverage: Negative, Neutral and Positive

Agenda

US Healthcare Coverage Landscape

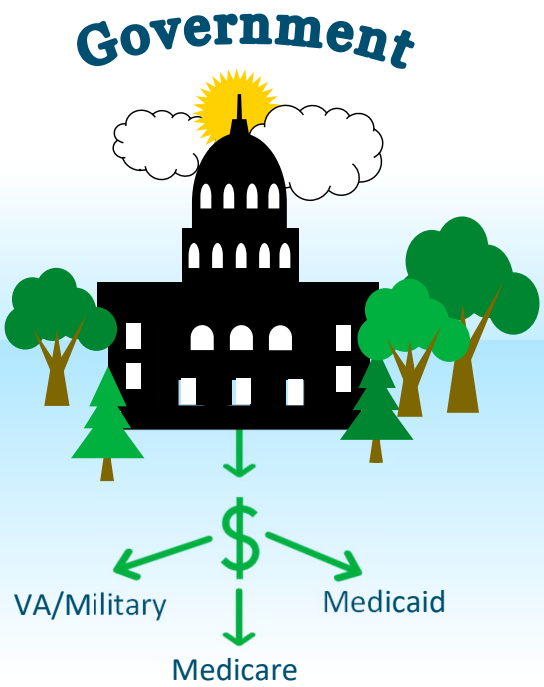
- Numbers and Flow
- Government Payers
- Other Insurance/Options

Commercial Payers

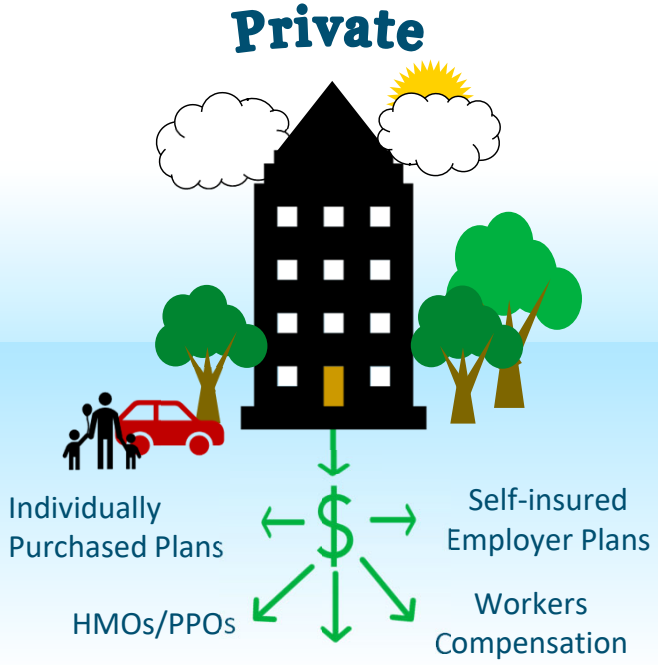
- Introduction and Size
- Multifaceted Approach
  - Influencers and Forces
  - Evidence is Key
  - Petition Process

US Healthcare Coverage Landscape

Who Pays for Healthcare?



118M individuals



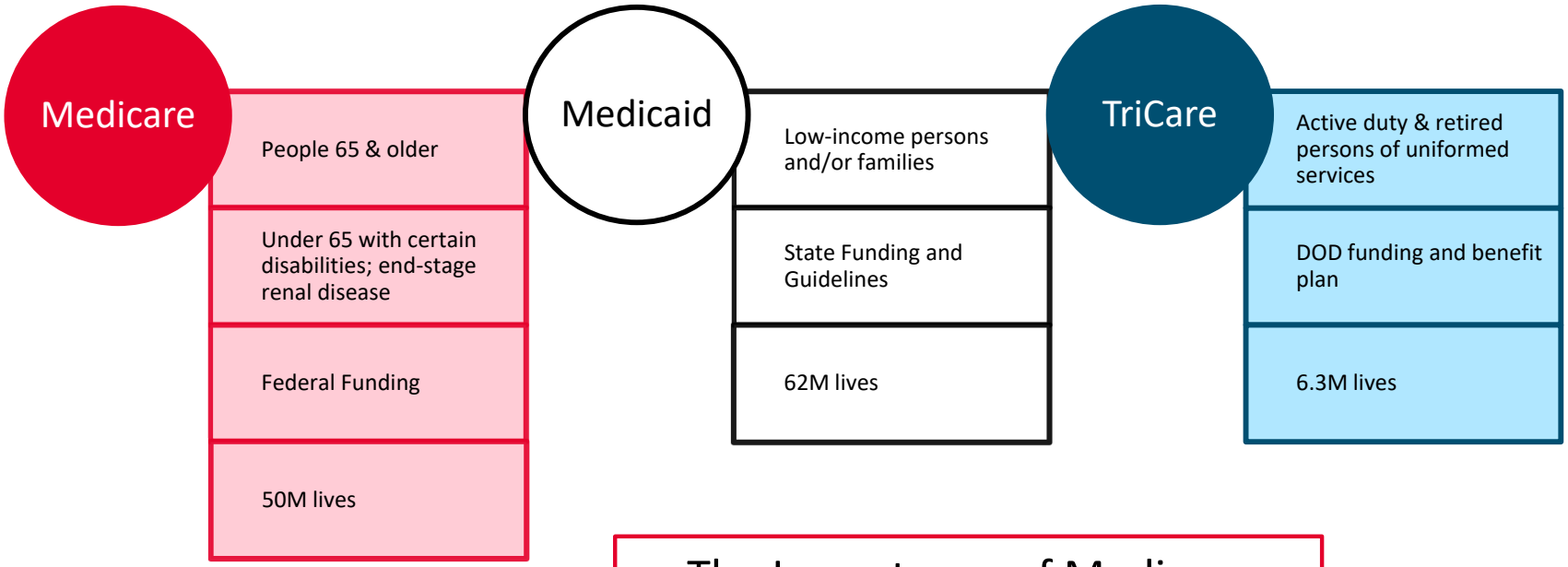
191M individuals

AHIP 2021, data on file.

[Health Insurance Coverage of the Total Population (CPS) | KFF]

328M Total Lives US

Insurance: Government Coverage

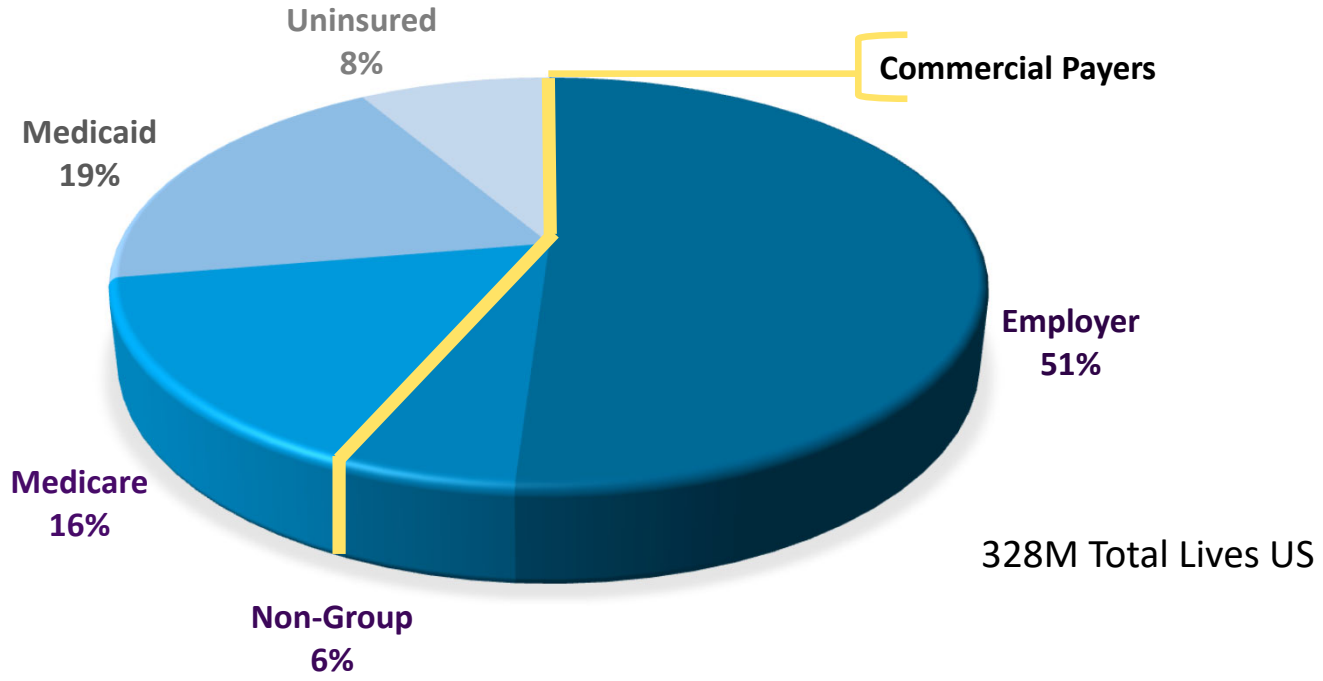


The Importance of Medicare

- ✓ Benchmark for coverage and payment
- ✓ Commercial payers watch Medicare

Commercial Payers

73% of US healthcare market composed of commercial based plans and Medicare



328M Total Lives US

Health Insurance Coverage of the Total Population (CPS) | KFF

Commercial Payers Who are they?

Anthem

bluecrossma.com

KAISER PERMANENTE

BlueCross BlueShield Association

CIGNA
A Business of Caring.

UnitedHealthcare
A UnitedHealth Group Company

HUMANA.
Guidance when you need it most

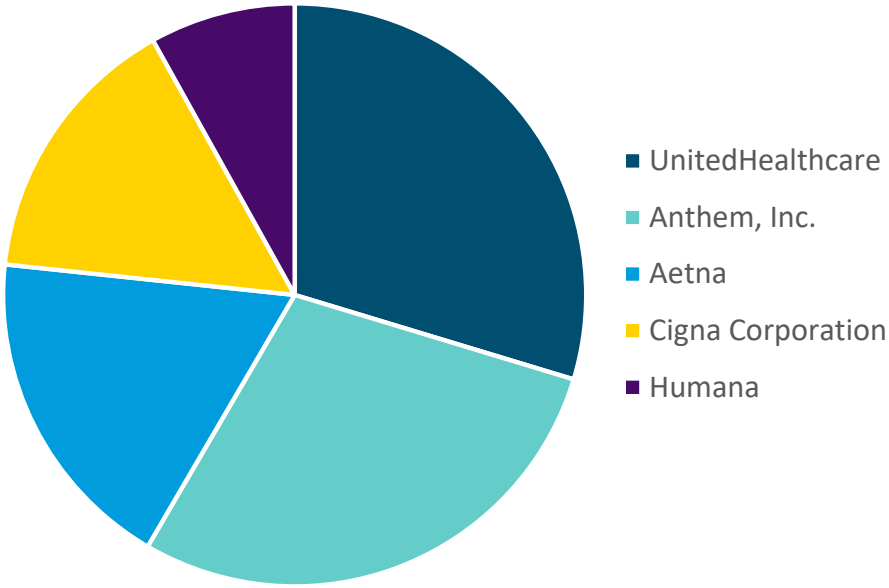
COVENTRY
Health Care

Aetna

Top 15 Commercial Payers represent 141 Million U.S. lives

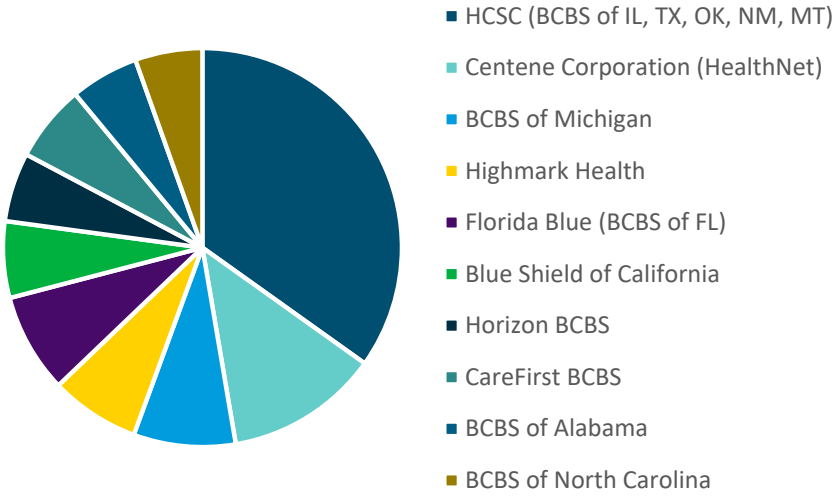
National Payers

97 Million Commercial Lives



Top 10 Regional Payers

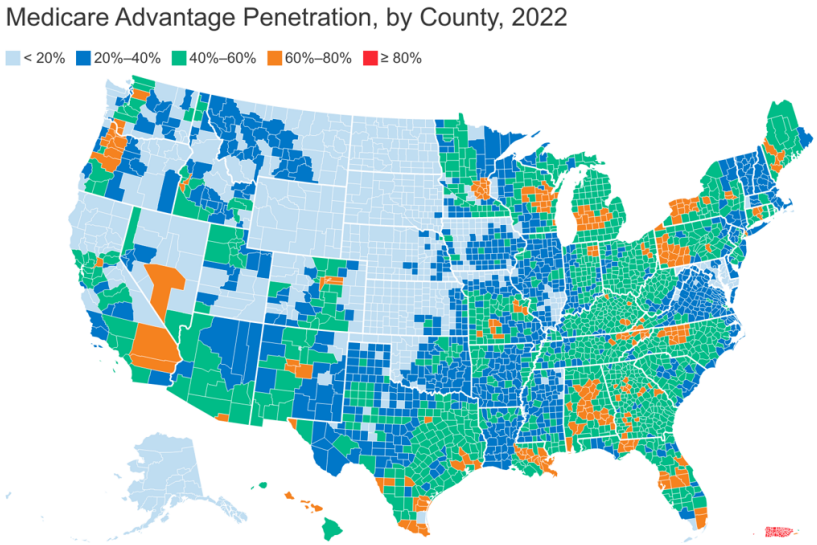
44 Million Commercial Lives



191 Million Commercial Covered Lives Total

AHIP 2021, data on file.

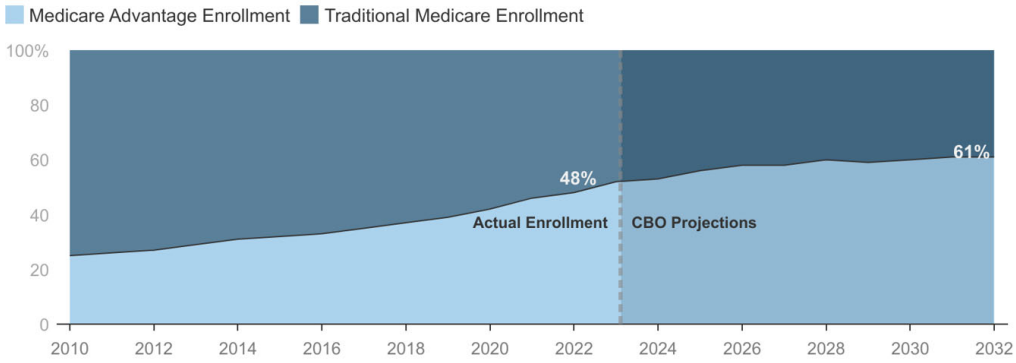
Medicare Advantage is the fastest growing segment and coverage is influenced by commercial policy



WITHOUT A NCD IN PLACE, MA PLANS FOLLOW COMMERCIAL COVERAGE POLICIES

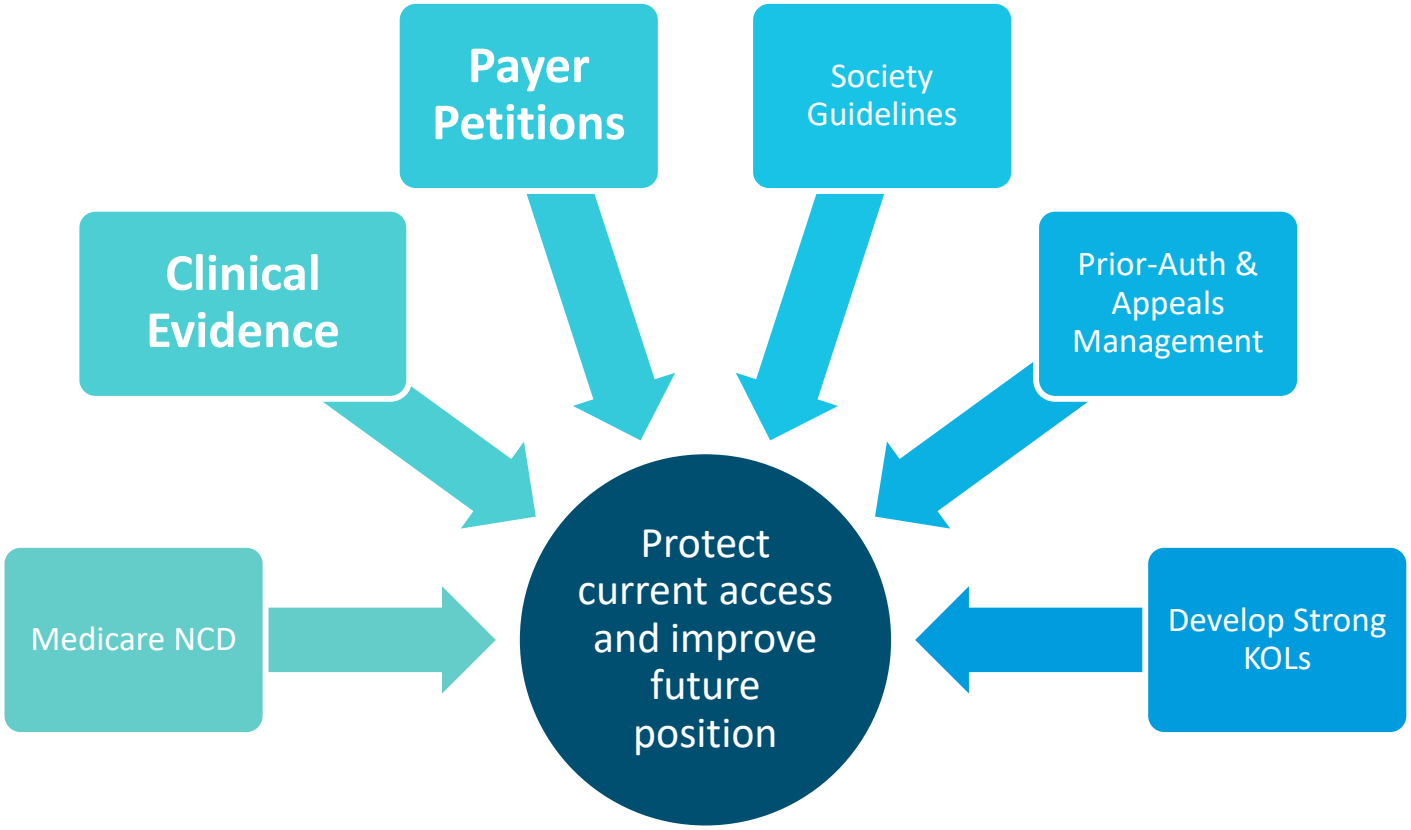
BY 2030 ADVANTAGE PLANS WILL ACCOUNT FOR ROUGHLY 60% OF MEDICARE COVERAGE

- Today the Medicare population nearly evenly split between traditional & advantage
  - Medicare Advantage = 24 million enrollees (48%)



KFF – Medicare Advantage in 2022: Enrollment Update and Key Trends

Commercial Coverage Requires a Multifaceted Approach



Influencers of Coverage Decisions

FDA evaluates *safety and efficacy*

Medicare and Commercial payers evaluate *medical necessity*

Societies establish *practice patterns and guidelines*

FDA Approval ≠ Payer Coverage ≠ Professional Society Guidelines

CMS Approval ≠ Commercial Coverage

Dueling Forces at Work

DRIVING FORCES

Breakthrough Science

Personalized Medicine

Technology, Big Data, Analytics

Patient Centered Outcomes
Clinical Trial Design

RESTRAINING FORCES

Inflation & Affordability

Industry Reputation Issues

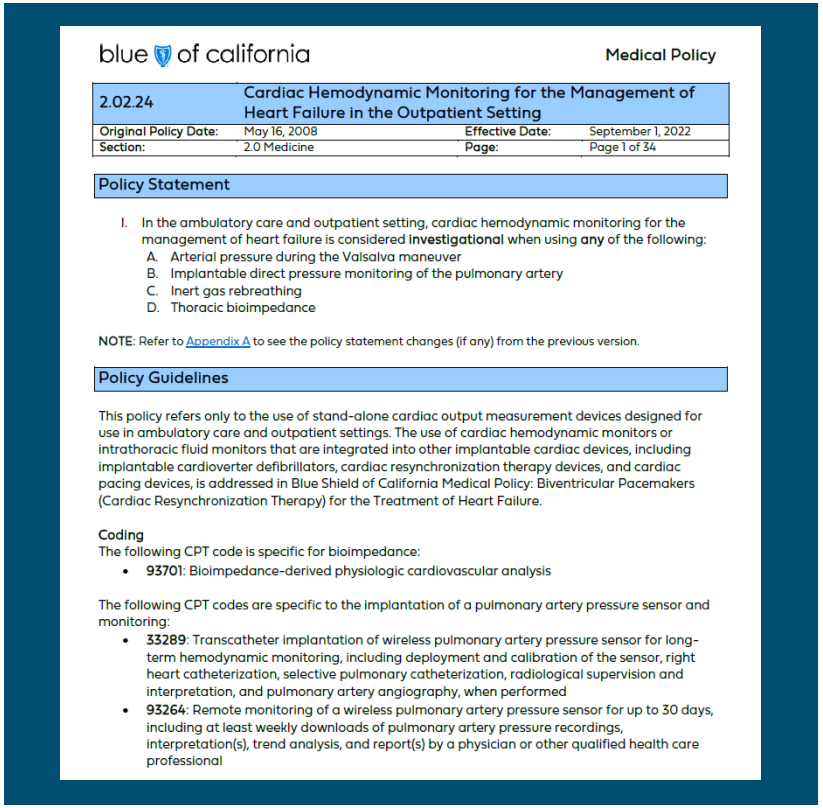
Differing Payment Models

Impact of Consolidation

Coverage Summary

COVERAGE = MEDICAL POLICY

- Health condition, illness, injury, disease or symptom for which the company will pay
  - Based on the most current research and indicates whether a technology, procedure, drug or device is
    1. Medically Necessary
    2. Experimental/investigational
- Each payer determines its own coverage policies
  - Employer funded plans determine what benefits (policies) they will offer employees
- Most plans policies are available
  - Includes background, coding, and definitions
  - Detailed rationale for/against coverage
  - References to peer-reviewed journals and other authoritative publications



blue of california — Medical Policy

2.02.24	Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting		
Original Policy Date:	May 16, 2008	Effective Date:	September 1, 2022
Section:	2.0 Medicine	Page:	Page 1 of 34

Policy Statement

I. In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring for the management of heart failure is considered **investigational** when using **any** of the following:
   A. Arterial pressure during the Valsalva maneuver
   B. Implantable direct pressure monitoring of the pulmonary artery
   C. Inert gas rebreathing
   D. Thoracic bioimpedance

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

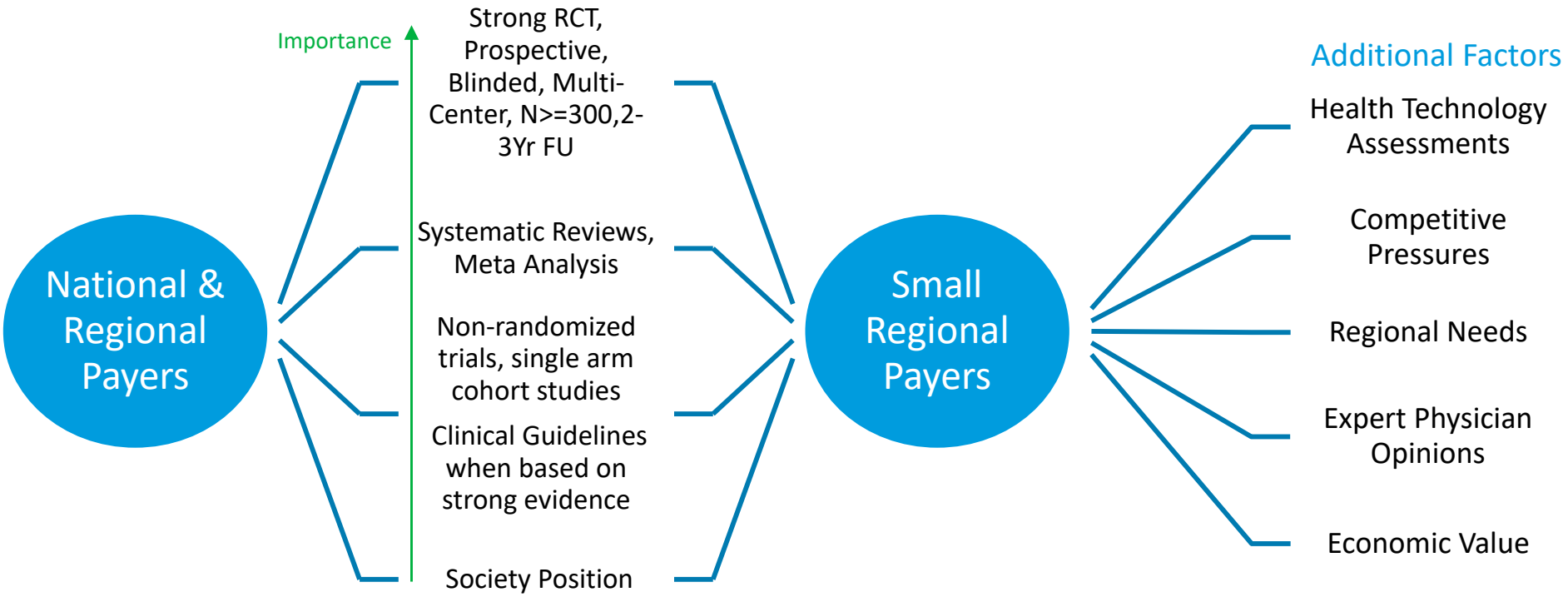
Policy Guidelines

This policy refers only to the use of stand-alone cardiac output measurement devices designed for use in ambulatory care and outpatient settings. The use of cardiac hemodynamic monitors or intrathoracic fluid monitors that are integrated into other implantable cardiac devices, including implantable cardioverter defibrillators, cardiac resynchronization therapy devices, and cardiac pacing devices, is addressed in Blue Shield of California Medical Policy: Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure.

Coding
The following CPT code is specific for bioimpedance:
- **93701**: Bioimpedance-derived physiologic cardiovascular analysis

The following CPT codes are specific to the implantation of a pulmonary artery pressure sensor and monitoring:
- **33289**: Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed
- **93264**: Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional

Evidence is KEY



Commercial Payer Review Schedule

2023 Medical Policy Review Month					
January	**February**	**March**	**April**	**May**	**June**
Humana Select Health (UT) Wellmark BCBS of TN HCSC (IL,MT,OK,NM,TX) Medical Mutual	BCBS of NE Kaiser Permanente PacificSource	CIGNA BCBS of WY Carefirst BCBS	HealthNet BCBS MI BCBS MA Regence BCBS	BCBS of SC Health New England Priority Health (MI) CareFirst Health Alliance Plan	BCBS of AR Harvard Pilgrim Aetna
July	**August**	**September**	**October**	**November**	**December**
BCBS of Kansas UPMC Health Plan BCBS AL BCBS ID Higmark BCBS W & NE NY	HighMark BCBS of LA Capital BCBS Horizon BCBS BCBS AZ Molina Healthcare Medica	Florida Blue HealthPartners BS of CA Excellus BCBS of ND Geisinger Premera BCBS	BCBS NC BCBS of MS Tufts Health Plan BCBS of KC BCBS RI	Anthem BCBS of MN	UHC University of Utah Health Plan

Medical Policy Review Process

R&D Policy Team

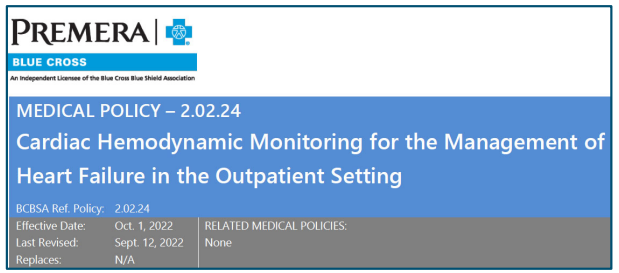
- Evaluate New Evidence
- Update Policy Position
- Annually Per National Commission of Quality Assurance (NCQA)

Clinical Policy Committee

- Reviews Draft Policy, Peer Literature, Relevant Society Positions
- Clinical Guidelines & Utility, Outcomes and Patient Experience
- Standard of Care

Finance and Actuary Review

- Essentially minimal impact
- Major Impact Requires Cost Study
  - Cost Study = Not Clinically Critical, Policy Hold



PREMERA BLUE CROSS

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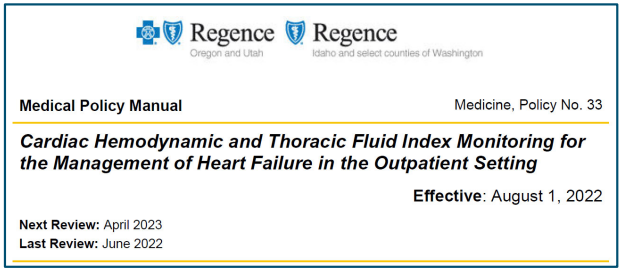
MEDICAL POLICY – 2.02.24

Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting

BCBSA Ref. Policy:	2.02.24	
Effective Date:	Oct. 1, 2022	RELATED MEDICAL POLICIES:
Last Revised:	Sept. 12, 2022	None
Replaces:	N/A	



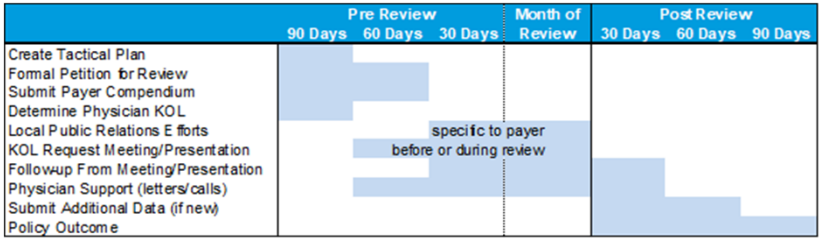
Regence Oregon and Utah | Regence Idaho and select counties of Washington

Medical Policy Manual Medicine, Policy No. 33

Cardiac Hemodynamic and Thoracic Fluid Index Monitoring for the Management of Heart Failure in the Outpatient Setting

Effective: August 1, 2022

Next Review: April 2023
Last Review: June 2022



Wrap-Up

COMMERCIAL COVERAGE REQUIRES A MULTIFACETED APPROACH

Clinical Evidence

- Requires more than '1 and Done'
- Strength of evidence

Payer Pressure

- Petition Payers annually
- Communicate new supporting clinical data, expansions, FDA approvals, etc.

Additional Areas of Focus

- Medicare Coverage
- Society Support
- Pre-Auth and Denial Management Programs
- KOL Development & Utilization

Abbott