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Reimbursement 101 Training: Introductory Topics

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Objectives

- Provide a very basic understanding of the structure of the US Healthcare System and components of reimbursement

- Impart awareness of underlying reimbursement concepts to enhance understanding of next level coverage, coding, and payment, as well as how evidence development supports reimbursement

Health Economics and Outcomes Research (HEOR) as Evidence Development

- What is your USP/target product profile (TPP) and how do you intend to generate evidence to support it?
- How much does an episode of care cost currently?
- What impact will your product have on the cost of an episode of care?
- How do you plan to quantify the improvement in health outcomes purported by use of your technology, e.g., via resource use, improved QoL?
- What is/are your health economic endpoint(s), e.g., cost avoidance, cost savings, cost-effectiveness, with different stakeholders?
- Is there a quality of life (QoL) aspect to your technology and, if so, do you plan to use it for an indication?
- What/who will be the focus/foci of your sales pitch? Will the buyers be the users and/or sales influencers, e.g., hospital administrators, KOLs?
- Do you plan to try for reimbursement OUS? If so, what are your plans to obtain reimbursement from various countries' health technology authorities?

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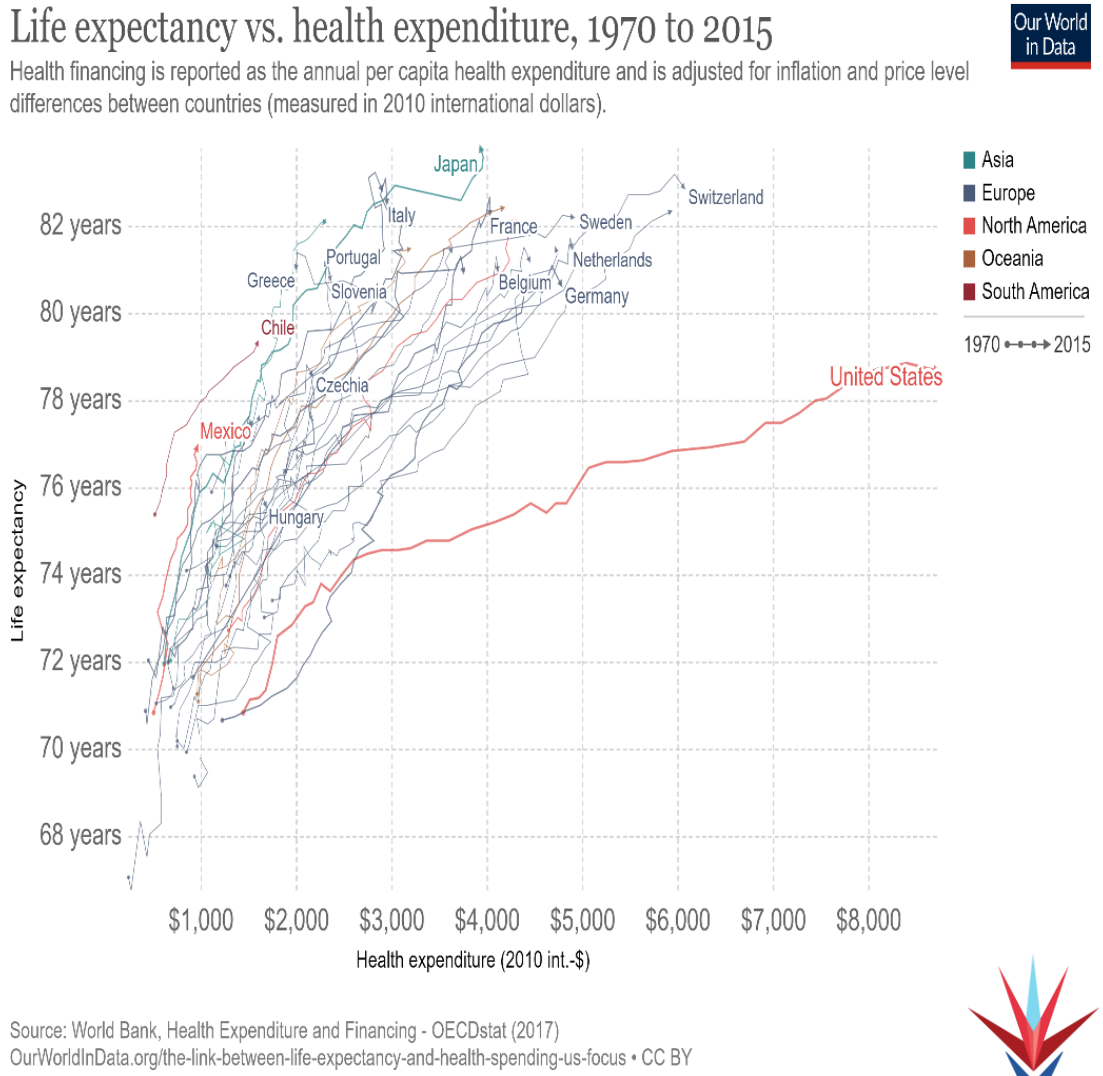
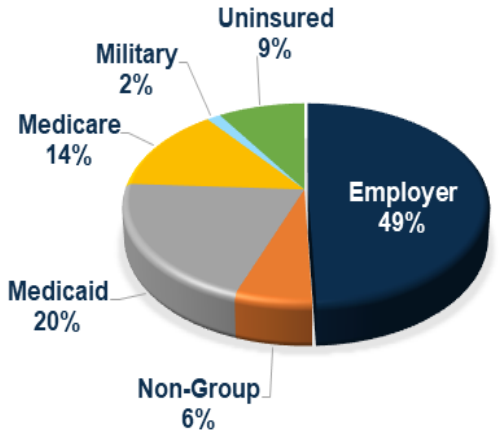
Overview of the US Healthcare System Macrolevel US Healthcare Cost Trends

- Since the 1970s, healthcare spend per capita in the US has increased significantly compared to that of other countries; despite this increased expenditure year over year, the US consistently ranks last among developed countries in life expectancy and overall patient population health
  - In 2011, people aged 80+ accounted for 24% of the Medicare population and 33% of Medicare spending; this dichotomy will become worse as models suggest the US population 65+ will double, 80+ will triple, and 90+ will quadruple by 2050
- As experts have come to realize that current cost growth trends are unsustainable, there have been several movements to identify ways to reduce costs including, but not limited to:
  - Repealing the ACA to reduce federal Medicaid spend
  - Progressive payment models to better align reimbursement to patient outcomes
  - An increasing focus by payers on health economics/cost-effectiveness
  - Various proposals to reduce drug spend (e.g., allow Medicare to negotiate drug prices)



Payers of Interest

Payers of Interest Depend on Target Patient Population for Your Technology



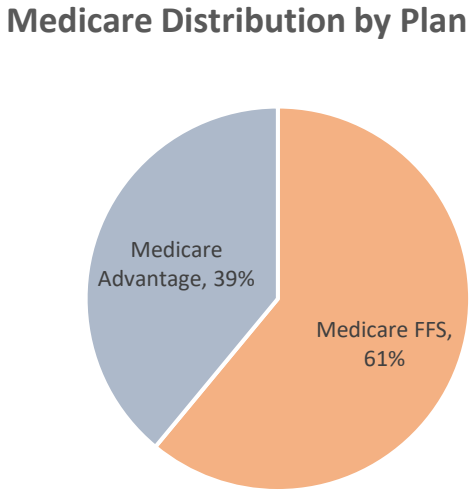
318.5 Million People in the US

Source: Kaiser Family Foundation Analysis of the US Census American Community Survey, 2018.

Third-Party Payer	Who is Eligible?
Commercial Insurers	Employer-based Insurance • Non-disabled adults under age 65 • Children up to age 26 Individual Market / Non-Group Insurance • Small businesses • Near-retirees
Medicaid	• Low-income families • Pregnant women and children • Low-income elderly • Blind or disabled adults
Medicare	• Age 65+ • Adults disabled > 2 yrs • End-stage renal disease

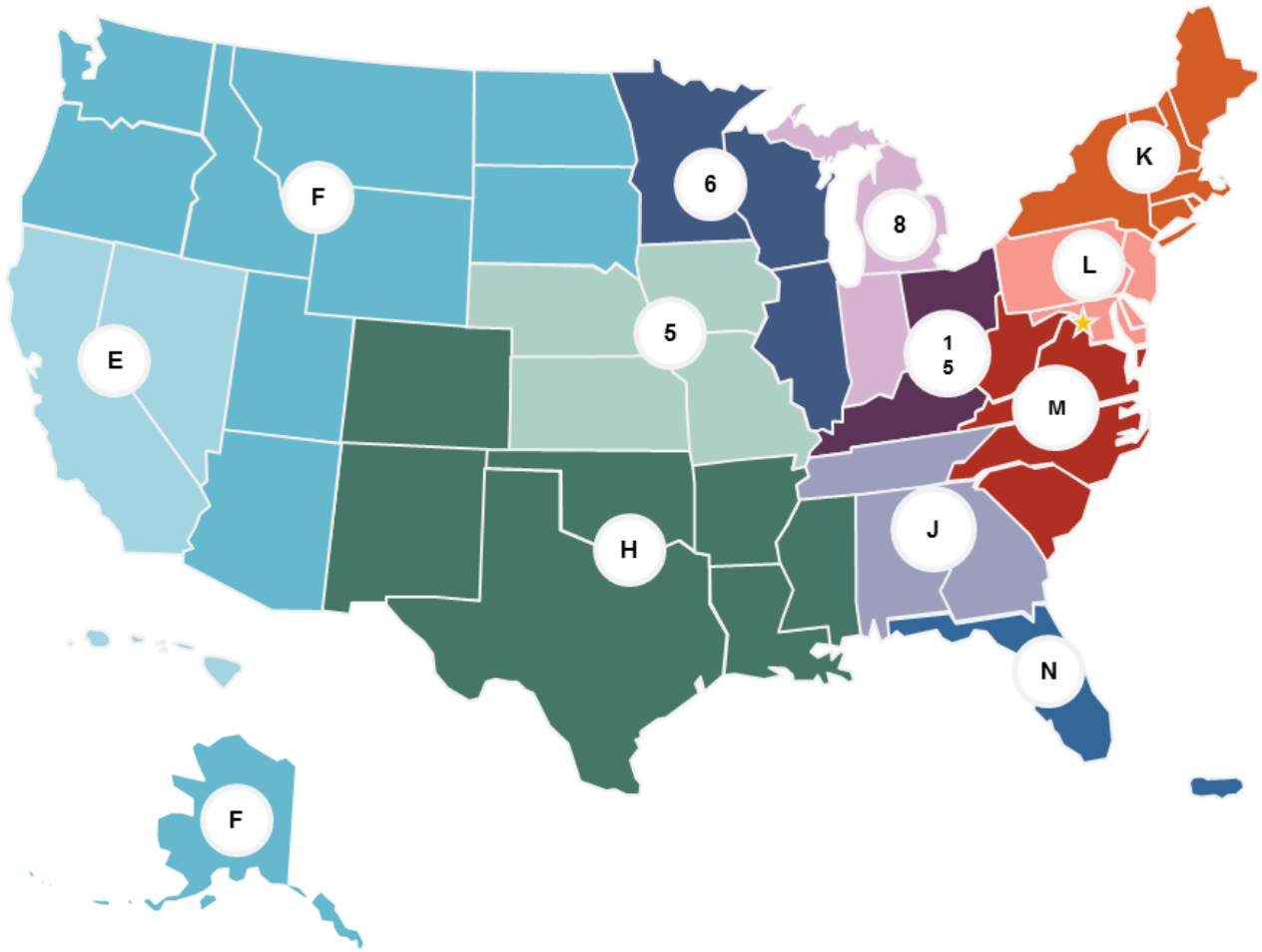
Overview of the US Healthcare System
Introduction to Medicare

- Medicare is the federal health insurance program for people 65 or older and certain younger people with disabilities; different parts of Medicare help cover specific services:
  - Part A (Hospital Insurance) – covers inpatient hospital stays, skilled nursing facility care, hospice care, and some home health
  - Part B (Medical Insurance) – covers certain doctors' services, outpatient care, medical supplies, and preventive services
  - Part C (Medicare Advantage Plans) – Part A and B benefits administered by commercial payers
  - MA plans must include products and services covered by Medicare FFS, but can provide expanded coverage
  - Part D (Prescription Drug Coverage) – Adds prescription drug care to original Medicare
- Medicare currently insures more than 62 million Americans and covered lives can be segmented into Medicare Fee-For-Service (FFS)—61% and Medicare Advantage—39%
- National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) are Medicare coverage policies that detail the requirements to establish a service as "reasonable and necessary"
  - NCDs are coverage decisions that are mandated at the national level and typically address disruptive, controversial, and/or high-cost items
  - LCDs are published by Medicare Administrative Contractors (MACs) and apply to their respective contracted coverage area
- The US Centers for Medicare and Medicaid Services (CMS) uses Medicare Administrative Contractors (MACs) to process claims, define parameters for coverage, and set payment rates in localized sectors in the US



Overview of the US Healthcare System
Current Medicare Part A/B MAC Landscape

E	**Noridian (Part A/B)** (CA, NV, HI, Guam, American Samoa, Northern Mariana Islands) *Contract dates:* 9/13/2013-9/2017
F	**Noridian (Part A/B)** (AK, AZ, ID, MT, ND, OR,SD, UT, WY, WA) *Contract dates:* 08/2011-8/31/2016
H	**Novitas (Part A/B)** (AR, CO, LA, MS, NM, OK, TX) *Contract dates:* 11/2011-2/28/2017
5	**Wisconsin Physicians Service (Part A/B)** (IA, KS, MO, NE) *Contract dates:* 07/2012-7/31/2017
6	**National Government Services (Part A/B)** (IL, MN, WI) *Contract dates:* 09/2012- 12/31/2017
8	**Wisconsin Physicians Service (Part A/B)** (IN, MI) *Contract dates:* 09/2011- 12/31/2016
N	**First Coast Service Options (Part A/B)** (FL, Puerto Rico, Virgin Islands) *Contract dates:* 2/14/2014-2/13/2019
J	**Cahaba GBA (Part A/B)** (AL, GA, TN) *Contract dates:* 9/17/2014-TBD
M	**Palmetto GBA (Part A/B)** (NC, SC, VA, WV) *Contract dates:* 8/2015-3/2020
L	**Novitas (Part A/B)** (DE, MD, NJ, PA) *Contract dates:* 09/2012-09/2017
K	**National Government Services (Part A/B)** (CT, MA, ME, NH, NY, RI, VT) *Contract dates:* 02/2013-02/28/2018
15	**CGS Administrators (Part A/B)** (KY, OH) *Contract dates:* 9/17/2015-TBD



The Medicare Part A/B landscape currently consists of 8 MACs that cover 12 jurisdictions; these MACs are responsible for processing claims for Medicare FFS beneficiaries in their respective geographies

Overview of the US Healthcare System
Current Medicare Molecular Diagnostics (MolDx) Landscape

- Medicare's Part A/B MACs are responsible for processing Medicare Moldx claims
- Noridian, WPS, and CGS have implemented Palmetto's MolDx Programs (6 of 12 jurisdictions covering 26 states) and thus follow Palmetto's Moldx coverage determinations

E	**Noridian (Part A/B)** (CA, NV, HI, Guam, American Samoa, Northern Mariana Islands)
F	**Noridian (Part A/B)** (AK, AZ, ID, MT, ND, OR,SD, UT, WY, WA)
H	**Novitas (Part A/B)** (AR, CO, LA, MS, NM, OK, TX)
5	**Wisconsin Physicians Service (Part A/B)** (IA, KS, MO, NE)
6	**National Government Services (Part A/B)** (IL, MN, WI)
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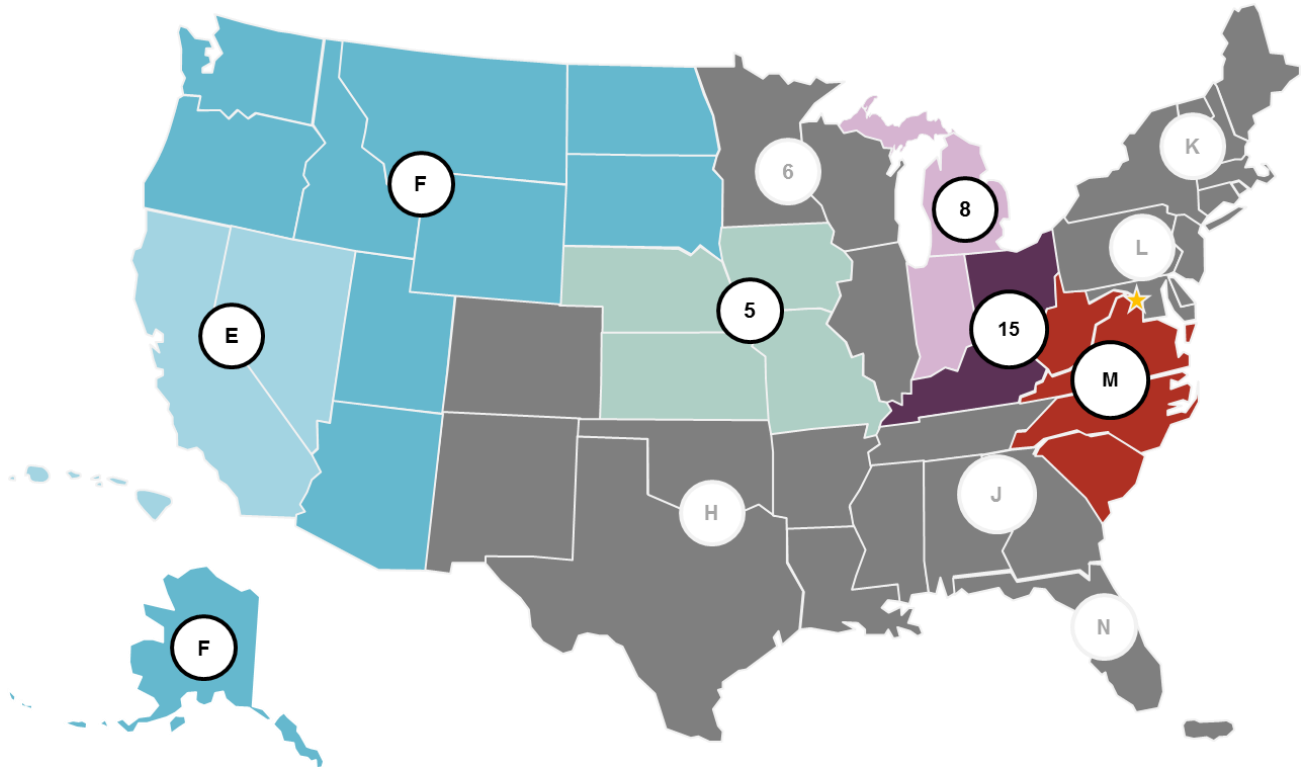
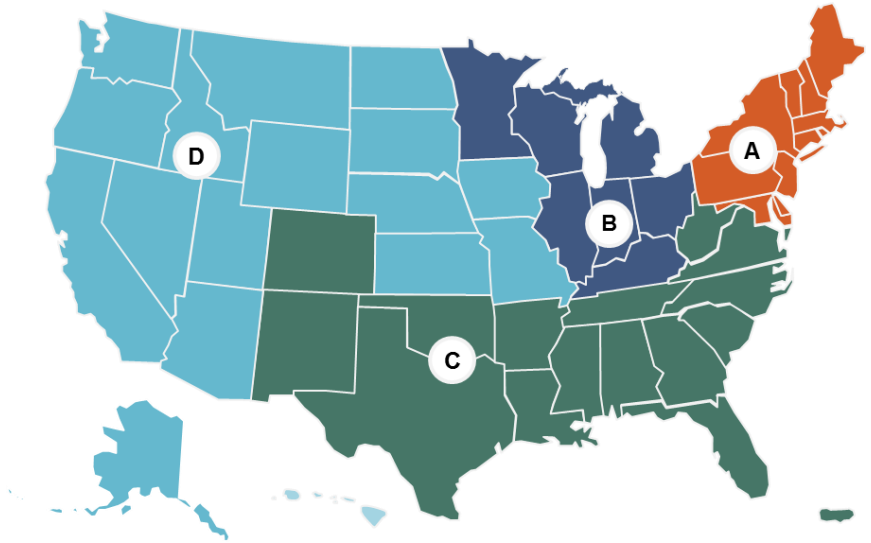


Overview of the US Healthcare System
Current Medicare Durable Medical Equipment (DME) MAC Landscape

- DME MACs process Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supply (DMEPOS) claims for defined geographic areas
- Currently, 2 DME MACs (Noridian and CGS) cover the 4 jurisdictions
- DMEPOS reimbursement is typically the lesser of the stated fee schedule amount or the provider's charge amount
- Some DMEPOS items are subject to competitive bidding in which DME suppliers for certain products are chosen as sole suppliers for an entire geographic area
- In addition, beneficiaries are typically responsible for a 20% coinsurance

DME Medicare Administrative Contractors (MACs)



A	Noridian Administrative Services
B	CIGNA Government Services
C	CIGNA Government Services
D	Noridian Administrative Services

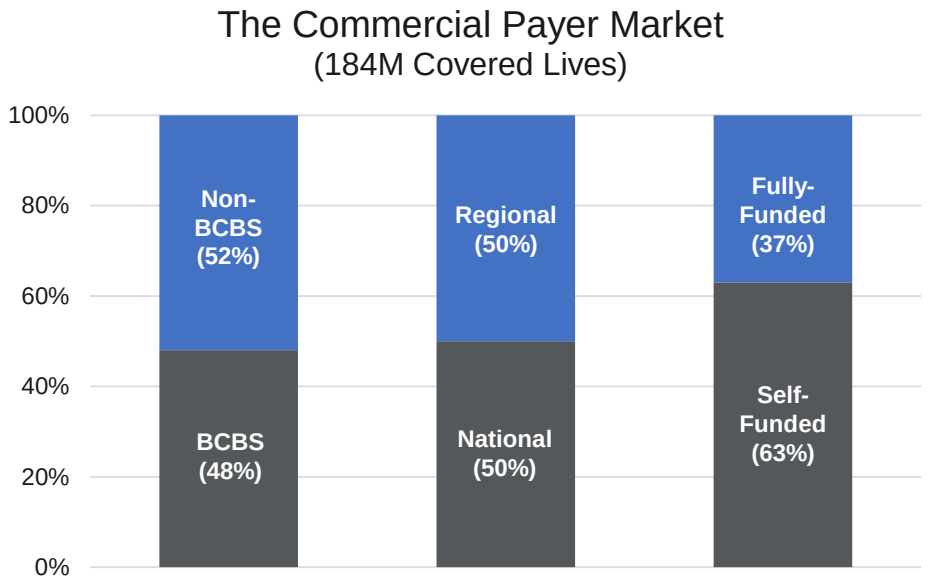
[1] CMS. 2021.
[2] CMS. Medicare Claims Processing Manual. Chapter 20 – DMEPOS

Overview of the US Healthcare System
Introduction to Medicaid

- Medicaid is a jointly funded, Federal-State health insurance program for eligible low-income adults, children, pregnant women, elderly adults and people with disabilities
- Each individual state manages their Medicaid program, including eligibility criterion (e.g., financials, record of employment, salary thresholds, and number of financial dependents)
- However, the ACA allowed individual states the option of whether or not to expand Medicaid to individuals up to 133% below the federal poverty line (FPL) and eliminated pre-existing categories one had to fall under to quality
  - 30 states chose to expand Medicaid, adding 17 million previously uninsured Americans to the program
  - 20 states chose not to expand Medicaid due to various budgetary concerns (e.g., over-enrollment bankrupting the state budget); those state open their residents to the ACA's mandate requiring individuals to purchase private health insurance or pay a penalty
  - As of April 2021, >80 million people are covered by Medicaid (April 2017, 69 million)
- Before the ACA, the federal government shared Medicaid costs with individual states, with the government paying 57% of the total amount
- Under the ACA, the federal government covered 100% of the bill from 2014-2017 for individual states that chose to expand Medicaid; between 2017-2020, the rate steadily decreased and the government now covers 90% 2020 and beyond

Overview of the US Healthcare System
Introduction to the Commercial Payer Market

- Approximately 158M covered commercial lives are managed under approximately 950 different commercial plans in the United States
- There are 34 BCBS plans, which manage 48% (~89M) of all commercial covered lives, and 146 Non-BCBS plans, which manage 52% (~96M) of all commercial covered lives
- Due to recent consolidation amongst large plans, the majority of commercial lives are now managed by national health plans representing 50% (93M) of all commercial lives
- Majority (63% / 117M) of commercial lives receive insurance through a self-funded employer



- A self-insured health plan is one which the employer assumes financial risk for providing health benefits to its employees
- In this relationship, the payer is financially de-risked and is paid by the employer on a fee basis for the services required to administer the plan (e.g., claims processing)
- Self-insured employers can customize plans to fit the needs of their workforce and therefore are not confined to existing payer coverage policies
- In a traditional fully-funded (e.g., full-risk) plan, the health plan assumes the financial risk for managing the beneficiary

Note: Commercial lives exclude Medicare Part D, Medicare Supplemental, Medicare Advantage, and Medicaid HMO
[1] Atlantic Information Services' (AIS) 2017 Directory of Health Plans

Overview of the US Healthcare System
Introduction to the Top 25 Commercial Payer Market

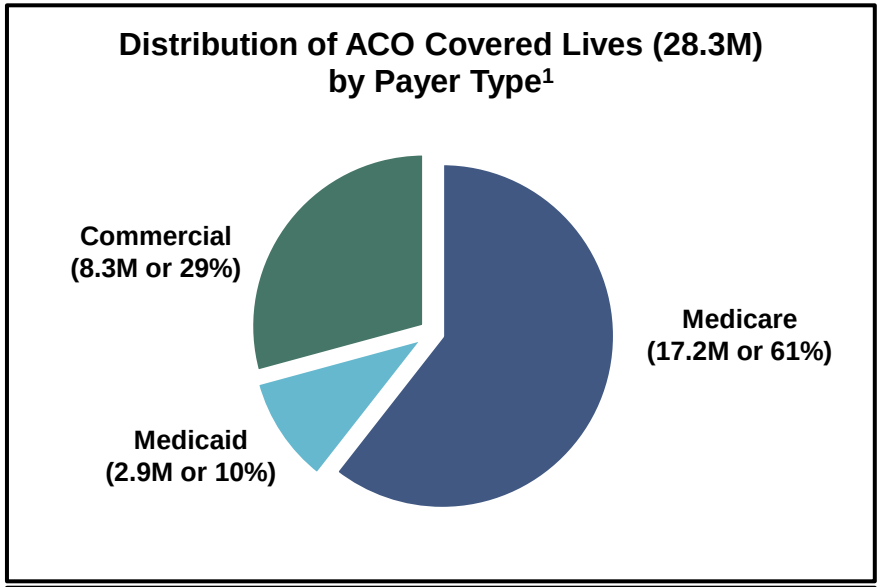
Payer	Covered Lives	Blues Affiliated	National/Regional
UHC	70,000,000	FALSE	Nationwide
Anthem	40,000,000	TRUE	Nationwide
Aetna	22,000,000	FALSE	Nationwide
Cigna	20,000,000	FALSE	Nationwide
HCSC	12,713,953	TRUE	Regional
Kaiser Permanente	9,348,510	FALSE	Regional
Centene / HealthNet	4,810,700	FALSE	Nationwide
Highmark	3,619,239	TRUE	Regional
BCBS MI	3,513,913	TRUE	Regional
BCBS FL	3,455,348	TRUE	Regional
CareFirst BCBS	3,167,202	TRUE	Regional
BS CA	3,104,128	TRUE	Regional
Horizon BCBS	2,787,222	TRUE	Regional
BCBS AL	2,620,098	TRUE	Regional
BCBS TN	2,604,100	TRUE	Regional
BCBS MA	2,486,968	TRUE	Regional
Cambia Health (Regence)	2,292,850	TRUE	Regional
BCBS NC	2,228,187	TRUE	Regional
Indep. BCBS	2,170,048	TRUE	Nationwide
Premera BC	2,069,189	TRUE	Regional
BCBS MN	1,879,863	TRUE	Regional
EmblemHealth	1,576,928	FALSE	Regional
BCBS LA	1,485,196	TRUE	Regional
Medical Mutual	1,353,637	FALSE	Regional
Wellmark BCBS	1,271,325	TRUE	Regional

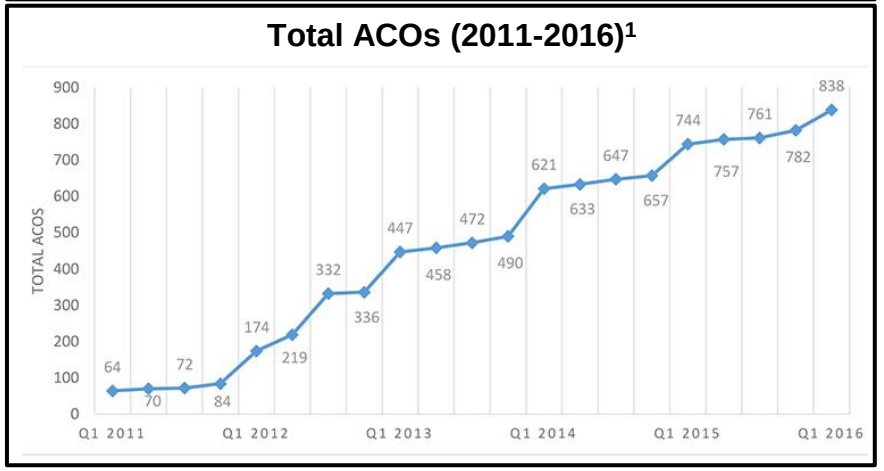
Note: Commercial lives exclude Medicare Part D, Medicare Supplemental, Medicare Advantage, and Medicaid HMO
[1] Atlantic Information Services' (AIS) 2017 Directory of Health Plans

- One would typically conduct commercial coverage landscape analyses of the top 25 payers (by commercial covered lives) as it provides a broad representation of the commercial market, including:
  - 85% of all commercial covered lives
  - 91% and 77% of BCBS and Non-BCBS commercial covered lives, respectively
  - 99% and 68% of national and regional commercial covered lives, respectively
- Commercial payers have varying evidence thresholds for coverage; however, national payers and BCBS plans tend to require the highest quality evidence

Overview of the US Healthcare System
Introduction to the Top 25 Commercial Payer Market

- Accountable Care Organizations (ACOs) are groups of physicians and/or hospitals that voluntarily assume the quality and cost of health care for a defined population of patients
  - ACOs may service both Medicare and Commercial members and currently comprise 61% and 29% of ACO lives, respectively
  - Examples of ACOs include Hackensack, Dignity Health, Tenet Healthcare and UCLA Health
- Unlike the traditional fee-for-service (FFS) model that pays providers for each service delivered, an ACO directly ties payment levels to patient outcomes, thereby incentivizing improved clinical outcomes and minimizing provider costs
- Over the last few years, the number of ACOs and covered lives have grown significantly





[1] HealthcareAffairs.org. Accountable Care Organizations in 2016: Private and Public-Sector Growth and Dispersion. 4/21/2016.

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DME
Reimbursement by CMS

- Medicare Part B and commercial insurers both consider medically necessary durable medical equipment (DME) as any equipment that is:

  - Durable (long-lasting)
  - Used for a medical reason
  - Not usually useful to someone who isn't sick or injured
  - Used in the patient's home

- DME that Medicare covers includes, but is not limited to:

  - Blood sugar monitors and test strips
  - Canes
  - Continuous passive motion machines
  - Hospital beds
  - Infusion pumps and supplies
  - Oxygen equipment and accessories
  - Manual and powered wheelchairs
  - Walkers; also applied to powered exoskeletons

https://www.bcbsnc.com/assets/providers/public/pdfs/dme_bluebook_rewrite.pdf;
https://www.medicare.gov/coverage/durable-medical-equipment-coverage.html

Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) *Definitions & Attributes*

- Durable Medical Equipment:
  - Can withstand repeated use;
  - Is primarily and customarily used to serve a medical purpose;
  - Generally, is not useful to a person in the absence of an illness or injury; and
  - Is appropriate for use in the home
- Prosthetics:
  - Devices that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ
- Orthotics:
  - Device, sometimes called a brace, applied to the outside of the body that supports a body part
- Supplies:
  - Usually disposable in nature;
  - Cannot withstand repeated use by more than one individual;
  - Are primarily and customarily used to serve a medical purpose;
  - Generally, are not useful to a person in the absence of illness or injury;
  - May be ordered and/or prescribed by a physician

CMS; Cigna; https://oig.hhs.gov/oei/reports/oei-02-95-00380.pdf

DMEPOS - Benefit Category and Product Class Alignment

Category	Durable Medical Equipment	Prosthetic	Orthotic	Supplies
Description	Durable (long-lasting); Used for a medical reason; Not usually useful to someone who isn't sick or injured; Used in the patient's home	Devices that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ	A brace includes rigid / semi-rigid devices that are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body	Supplies are used in conjunction with medically necessary DME, Prosthetic, or Orthotic products
Coding	HCPCS E-Codes	HCPCS L-Codes	HCPCS L-Codes	HCPCS A-Codes
Payment	DMEPOS Fee Schedule			

Medicare Claims Processing Manual
Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Orthotic

These appliances are covered under Part B as a medical or other health service (§1861(s)(9) of the Act) when furnished incident to physicians' services or on a physician's order. A brace [orthotic] includes rigid and semi-rigid devices that are **used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.**

Prosthetic

Prosthetic devices (other than dental) are covered under Part B as a medical or other health service (§1861(s)(8) of the Act) and are devices that **replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ**. Replacements or repairs of such devices are covered when furnished incident to physicians' services or on a physician's orders.

HCPCS = Healthcare Common Procedure Coding System

Fee Schedules for DMEPOS Products

- CMS manages a national DMEPOS fee schedule which sets prices based on the nature of the item and its associated product group
- Items are placed into 5 categories, each of which have different methodologies for determining payment:
  1. Inexpensive and other routinely purchased items
  2. Frequently serviced items
  3. Oxygen and oxygen equipment
  4. Other covered items (other than DME)
  5. Capped rental items
- CMS sets payment rates for frequently serviced items by taking the weighted average of all local payment amounts
  - Local payment amounts are determined by regional MAC on a case-by-case basis
  - Data are necessary to set local or national payment rates
- In instances where HCPCS codes are not included in CMS' National DME Fee Schedule, individual DME MACs may price these HCPCS codes in their respective regional DME Fee Schedules

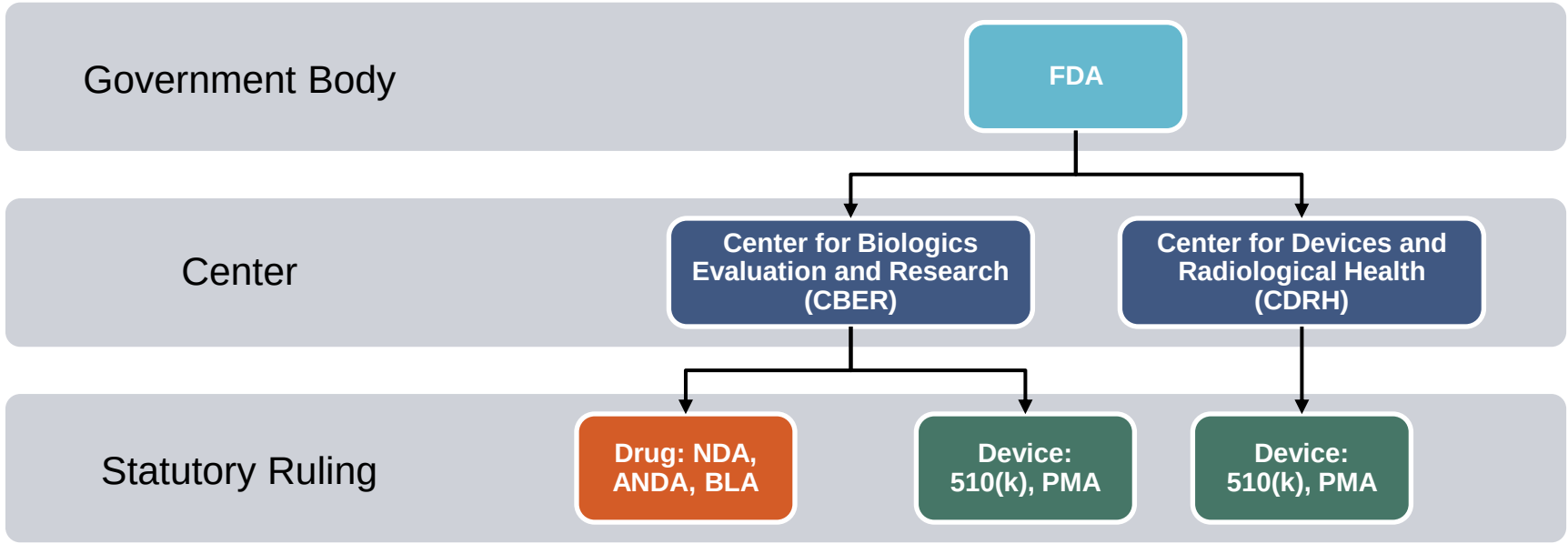
DMEPOS - Coding Dynamics

- The Pricing, Data Analysis and Coding (PDAC) contractor maintains the Durable Medical Equipment Coding System (DMECS)
- Noridian Healthcare Solutions, LLC has served as PDAC contractor since August 2008

noridian
Healthcare Solutions

- Receives, evaluates and processes coding verification applications for DMEPOS
  - Coding verification is the process that allows manufacturers/distributors to request a coding decision on a DMEPOS item
- Provides coding guidance for manufacturers and suppliers on the proper use of the Healthcare Common Procedure Coding System (HCPCS)

Impact of Regulatory Pathway on Reimbursement



- The most important factor in payers' determination of how to reimburse a technology is its regulatory pathway, not the center granting approval
- Given that some products (e.g., implantable biologics) have features that would qualify it as either a drug or device, CBER may also have the ability to regulate some devices
- While there is legacy for devices to be reimbursed as drugs (e.g., viscosupplements for knee osteoarthritis), all recent case studies of pre-market approvals (PMAs) clearly show that payers do not reimburse them as drugs but package reimbursement as part of the device procedure

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Reimbursement Codes
Introduction to Codes & Overview of Key Systems

- Codes are mechanisms which allow for uniform documentation and communication across healthcare entities including facilities, physicians, and payers

Coding System	Description	Administrative Body	Setting of Care	Example
Current Procedural Terminology **(CPT)**	5-digit numeric codes used to report medical, surgical, and diagnostic services provided by physicians or outpatient facilities	American Medical Association (AMA)	All (Physician office, inpatient, outpatient, ASC, etc.)	**36515 -** Therapeutic apheresis; with extracorporeal immunoadsorption and plasma reinfusion
Healthcare Common Procedure Coding System **(HCPCS)**	Alphanumeric codes describing specific items provided in the delivery of healthcare (may also include codes for services not described by CPT codes)	Centers for Medicare and Medicaid Services (CMS)	All (Physician office, inpatient, outpatient, ASC, etc.)	**S2120 –** Low density lipoprotein (LDL) apheresis using heparin-induced extracorporeal LDL precipitation
International Classification of Diseases, 9th Edition, Clinical Modification **(ICD-9)***	(Diagnosis Codes) 3 to 5 digit numeric codes used to report on the patient's condition or disease state	National Center for Health Statistics (NCHS/CDC)	Inpatient Only	**516.30** – Idiopathic interstitial pneumonia, not otherwise specified idiopathic fibrosing alveolitis
	(Procedure Codes) 3 to 4 digit numeric codes used to report medical and surgical services provided to the patient in the inpatient setting	CMS	Inpatient Only	**99.76** – Extracorporeal immunoadsorption
International Classification of Diseases, 10th Edition, Clinical Modification **(ICD-10)***	(Diagnosis Codes) 3 to 7 digit numeric codes used to report on the patient's condition or disease state	Centers for Disease Control and Prevention (CDC)	Inpatient Only	**M60.111** – Interstitial myositis, right shoulder

The transition from ICD-9-CM to ICD-10-CM occurred on October 1, 2015; ICD-11-CM will occur on January 1, 2022

HCPCS Coding Systems

Category	Description	Commentary
Level I	CPT Codes; physician services, lab tests	Updated annually by AMA
Level II	Products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)	Updated quarterly by CMS

* The transition from ICD-9-CM to ICD-10-CM occurred on October 1, 2015; ICD-11-CM will occur on January 1, 2022

Categories of CPT Codes

Category	Description	Commentary
I	distinct medical procedures or services	Range from 00100–99499; generally ordered into sub-categories based on procedure/service type and anatomy. Updated annually and effective for use on Jan. 1 of each year.
II	supplemental tracking or performance measurement codes	updated three times a year in March, July, and November by the CPT Editorial Panel.
III	new and emerging technologies to allow data collection and assessment of new services and procedures	justify establishment of a permanent Category I CPT code; Payers often deny claims involving Category III codes as “experimental” precisely because these code are for “new and emerging technologies.”

Introduction to Providers & Settings of Care
Facility & Non-Facility Definition

- CMS' Medicare Physician Fee Schedule (MPFS) lists physician payment rates by CPT code; physician payment may differ by the setting of care in which the physician service is performed (facility or non-facility)
- Facilities are hospitals (inpatient/outpatient), ambulatory surgical centers, skilled nursing facilities, nursing homes, or any other place that bills for Medicare
  - Some physicians are employed and work out of a hospital-owned facility; these physicians would bill based on CMS facility rates
  - Facility rates for physicians' services are lower than non-facility rates because the hospital receives separate payment for overhead and other related costs
- Non-facility refers to services performed in the physician office setting of care
  - Physician non-facility payment rates are higher because the physician bears the overhead expense for performing that service

Reimbursement Mechanisms by Setting of Care

	Physician Services	Inpatient Hospital (> 2 midnight stay)	Outpatient Hospital (< 2 midnight stay)	DMEPOS	Laboratory Diagnostics
Payment	▪ A discrete payment for physician services ▪ Payment is based on time/intensity, expense to the practice/facility, and malpractice premiums	▪ A discrete payment for the costs of care per inpatient stay/discharge ▪ Payments based on the patient's condition and treatment strategy	▪ A discrete payment for the cost of care per outpatient discharge ▪ Payments are grouped based on clinical and cost similarities of procedures	▪ A discrete payment for equipment that provides therapeutic value in the home setting ▪ Reimbursed on a fee schedule set by CMS	▪ A discrete payment for laboratory services ▪ Payments are based on the methodology and resources required by laboratory personnel to perform a test
Mechanism	Fee-for-service	Bundled	Quasi-bundled	Fee-for-service	Fee-for-service
Coding	Current Procedural Terminology (CPT)	ICD-10 Diagnosis and Procedure Codes	CPT	HCPCS	CPT (includes PLA, MAAA, etc.) Z-Code
Medicare Systems	Medicare Physician Fee Schedule (MPFS)	Medicare Severity - Diagnosis Related Groups (MS-DRGs)	Ambulatory Payment Classifications (APCs)	DME, Prosthetics / Orthotics, Supplies Fee Schedule (DMEPOS)	Clinical Lab Fee Schedule (CLFS)
Commercial Systems	Fee schedule	Per-diem or DRG methodology	APC methodology, payment > Medicare	Fee schedule, may be higher or lower than Medicare	Fee schedule

DMEPOS: Durable Medical Equipment, Prosthetics, Orthotics, Supplies

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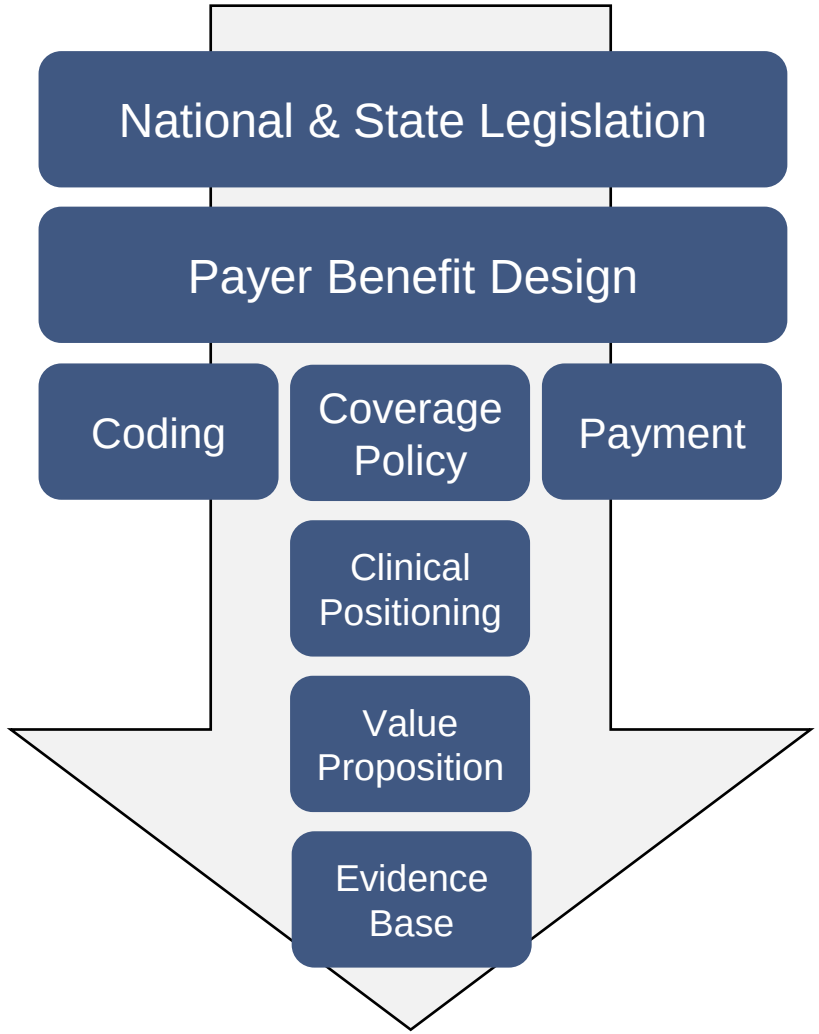
Interplay of Reimbursement Components
Market Access Cascade

- Legislation on the national and state levels may mandate that payers (insurers) cover specific treatments and/or indications
  - Mandates are typically pushed through the legislative process by influential politicians and target vulnerable or underserved populations (e.g., pediatric, elderly, etc.)
  - Legislative language can be purposefully vague to allow payers to set guidelines for determining “medical necessity”
- Payers use benefit design to determine how a treatment is managed from both an administrative and reimbursement perspective
  - Medicare’s benefit categories are statutorily defined
  - If a technology does not fall into an existing Medicare benefit category, it is statutorily excluded from Medicare coverage
- If a technology fits under an existing category, then access is determined by each individual payer’s evaluation of medical necessity
  - Determinations of medical necessity are made by evaluating evidence, which encompasses the positioning and inherent value of the technology
  - These evidence evaluations can be found in payer coverage policies

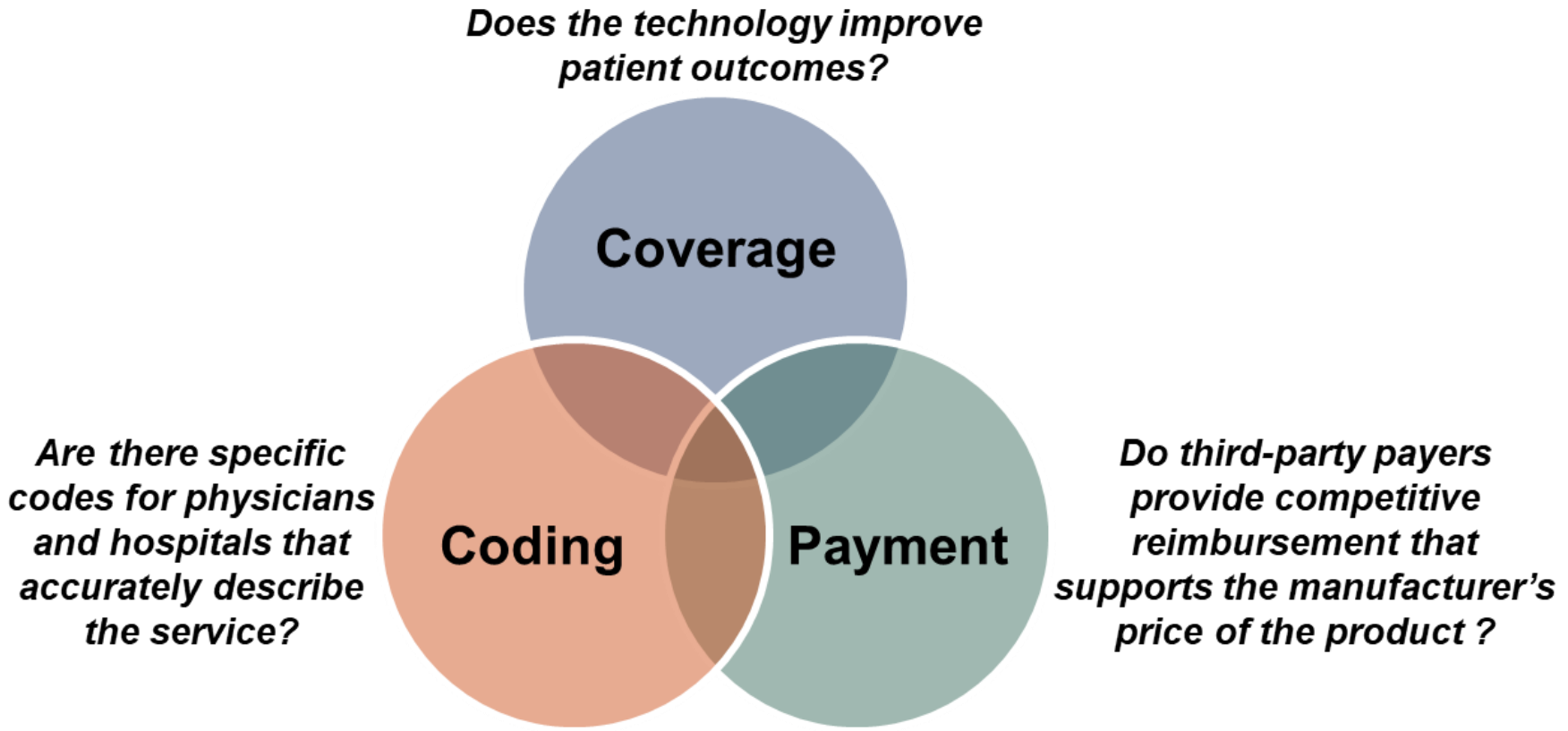


Interplay of Reimbursement Components
Clinical Utility

- The real-world viability of a test or device depends on the willingness of insurers to pay for its use; this depends on the ability to demonstrate that the test or device has clinical utility.
- Positive clinical utility encompasses improved patient outcomes:
  - Patient-focused endpoints such as hospital readmission, length of stay, morbidity and mortality
  - Patient functional outcomes such as cognitive ability, activities of daily living and patient quality of life (using validated patient reported outcomes [PROs] instruments)
  - Patient burden, risk or cost for the same or better outcome (cost-effectiveness)
- Direct evidence of link between intervention and clinical outcomes
  - RCTs
  - Observational studies
- Public and private payers moving towards value-based reimbursement via bundled payments and accountable care organizations (ACOs); providers at financial risk for improving patient outcomes and reducing overall costs

Developing Clinical Evidence for Regulatory and Coverage Assessments in *In Vitro* Diagnostics (IVDs). A Report of the IVD Clinical Evidence Working Group of the Medical Device Innovation Consortium (MDIC). August 13, 2019.

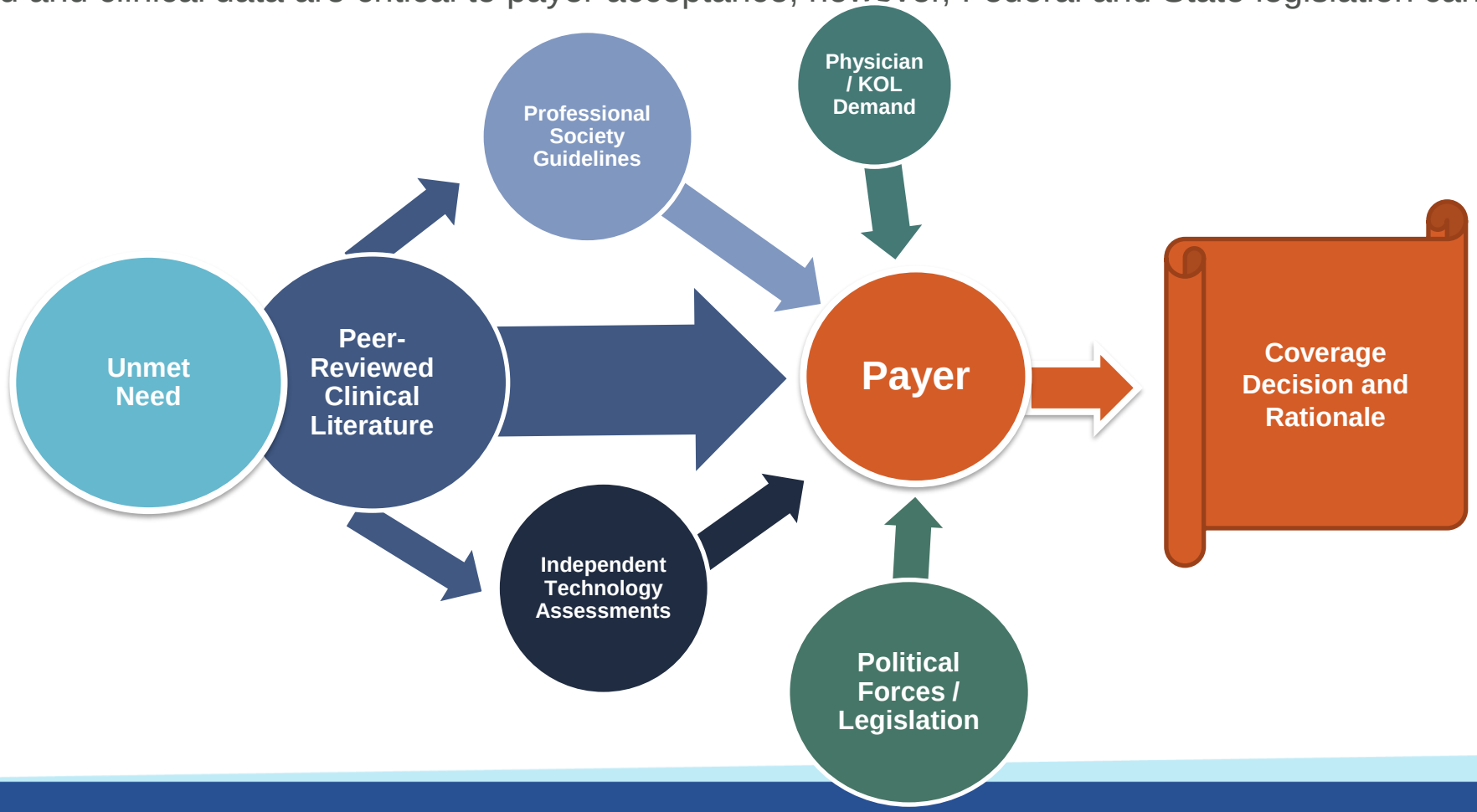
Interplay of Reimbursement Components
Components of a Successful Reimbursement Strategy



- Central to reimbursement success is the interaction between positive payer coverage policies, descriptive coding, and adequate payment to support price
- First and foremost, establishing payer coverage is vital to a successful reimbursement strategy

Interplay of Reimbursement Components
Multiple Factors Influence Payer Coverage Decisions

- Multiple factors determine whether a payer will provide coverage for a given technology, with some factors carrying more weight than others
- Unmet need and clinical data are critical to payer acceptance; however, Federal and State legislation can also play a critical role

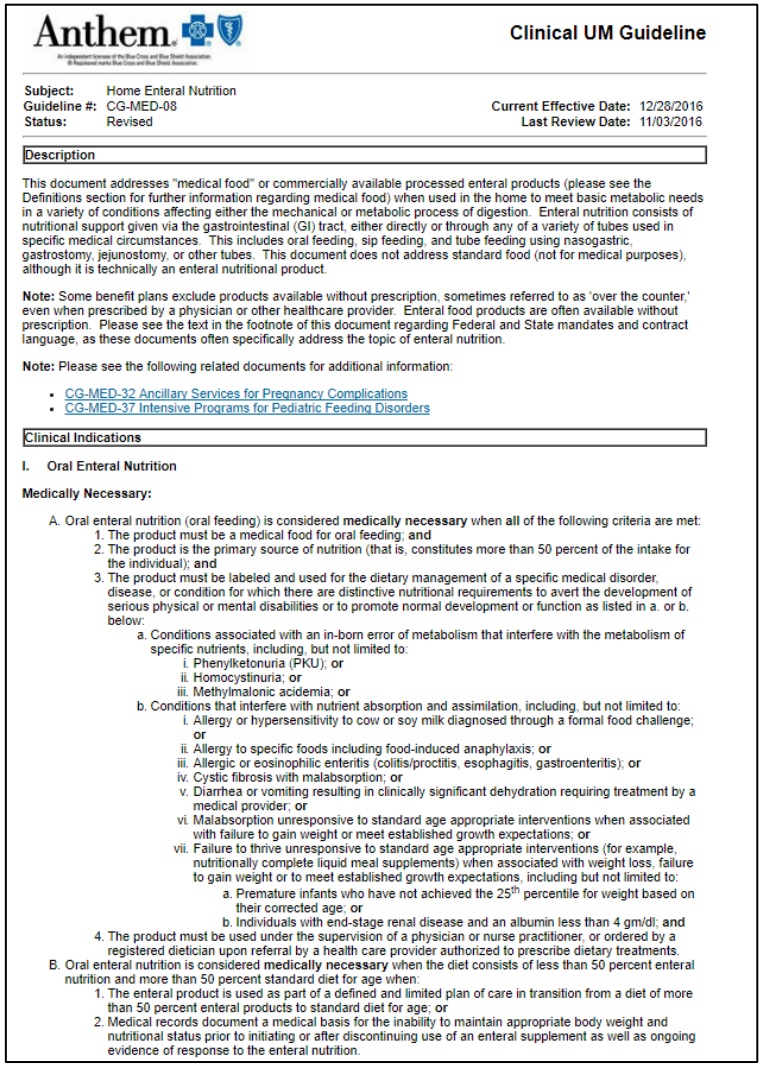


Interplay of Reimbursement Components
Introduction to Payer Coverage Policies – Medical Benefit

- **Payers develop medical policies to describe the conditions and/or restrictions of coverage including:**
  - Which products and indications are considered medically necessary or not medically necessary
  - Utilization restrictions (e.g., step therapy, prior authorization)
  - Position statement rationale

- **There are several triggers which could cause payers to develop a new coverage policy including:**
  - High procedure volume and/or impact on the payer's annual budget
  - High treatment cost per patient
  - High demand for the procedure from members and/or in-network physicians
  - Concerns over safety and/or efficacy

- **Payers typically maintain and update coverage policies on an annual basis**
  - This can involve updates to coverage rationale and/or determination, medical necessity, and coding



Anthem

Clinical UM Guideline

Subject: Home Enteral Nutrition
Guideline #: CG-MED-08
Status: Revised
Current Effective Date: 12/28/2016
Last Review Date: 11/03/2016

Description

This document addresses "medical food" or commercially available processed enteral products (please see the Definitions section for further information regarding medical food) when used in the home to meet basic metabolic needs in a variety of conditions affecting either the mechanical or metabolic process of digestion. Enteral nutrition consists of nutritional support given via the gastrointestinal (GI) tract, either directly or through any of a variety of tubes used in specific medical circumstances. This includes oral feeding, sip feeding, and tube feeding using nasogastric, gastrostomy, jejunostomy, or other tubes. This document does not address standard food (not for medical purposes), although it is technically an enteral nutritional product.

Note: Some benefit plans exclude products available without prescription, sometimes referred to as 'over the counter,' even when prescribed by a physician or other healthcare provider. Enteral food products are often available without prescription. Please see the text in the footnote of this document regarding Federal and State mandates and contract language, as these documents often specifically address the topic of enteral nutrition.

Note: Please see the following related documents for additional information:

- CG-MED-32 Ancillary Services for Pregnancy Complications
- CG-MED-37 Intensive Programs for Pediatric Feeding Disorders

Clinical Indications

I. Oral Enteral Nutrition

Medically Necessary:

A. Oral enteral nutrition (oral feeding) is considered **medically necessary** when **all** of the following criteria are met:
1. The product must be a medical food for oral feeding; **and**
2. The product is the primary source of nutrition (that is, constitutes more than 50 percent of the intake for the individual); **and**
3. The product must be labeled and used for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements to avert the development of serious physical or mental disabilities or to promote normal development or function as listed in a. or b. below:
   a. Conditions associated with an in-born error of metabolism that interfere with the metabolism of specific nutrients, including, but not limited to:
      i. Phenylketonuria (PKU); **or**
      ii. Homocystinuria; **or**
      iii. Methylmalonic acidemia; **or**
   b. Conditions that interfere with nutrient absorption and assimilation, including, but not limited to:
      i. Allergy or hypersensitivity to cow or soy milk diagnosed through a formal food challenge; **or**
      ii. Allergy to specific foods including food-induced anaphylaxis; **or**
      iii. Allergic or eosinophilic enteritis (colitis/proctitis, esophagitis, gastroenteritis); **or**
      iv. Cystic fibrosis with malabsorption; **or**
      v. Diarrhea or vomiting resulting in clinically significant dehydration requiring treatment by a medical provider; **or**
      vi. Malabsorption unresponsive to standard age appropriate interventions when associated with failure to gain weight or meet established growth expectations; **or**
      vii. Failure to thrive unresponsive to standard age appropriate interventions (for example, nutritionally complete liquid meal supplements) when associated with weight loss, failure to gain weight or to meet established growth expectations, including but not limited to:
         a. Premature infants who have not achieved the 25th percentile for weight based on their corrected age; **or**
         b. Individuals with end-stage renal disease and an albumin less than 4 gm/dl; **and**
4. The product must be used under the supervision of a physician or nurse practitioner, or ordered by a registered dietician upon referral by a health care provider authorized to prescribe dietary treatments.

B. Oral enteral nutrition is considered **medically necessary** when the diet consists of less than 50 percent enteral nutrition and more than 50 percent standard diet for age when:
1. The enteral product is used as part of a defined and limited plan of care in transition from a diet of more than 50 percent enteral products to standard diet for age; **or**
2. Medical records document a medical basis for the inability to maintain appropriate body weight and nutritional status prior to initiating or after discontinuing use of an enteral supplement as well as ongoing evidence of response to the enteral nutrition.

Interplay of Reimbursement Components
Interpretation of Payer Coverage Policies

Explicit Coverage	• Policy explicitly states conditions for coverage and defines utilization restrictions
Silent or Case-by-Case Coverage	• No published policy; coverage may be conferred on a case-by-case basis
Implicit Non-Coverage	• Published policy stipulates non-coverage for all patients outside of published coverage criteria (e.g., non-covered for all other indications)
Explicit Non-Coverage	• Published policy explicitly stipulates non-coverage for all patients

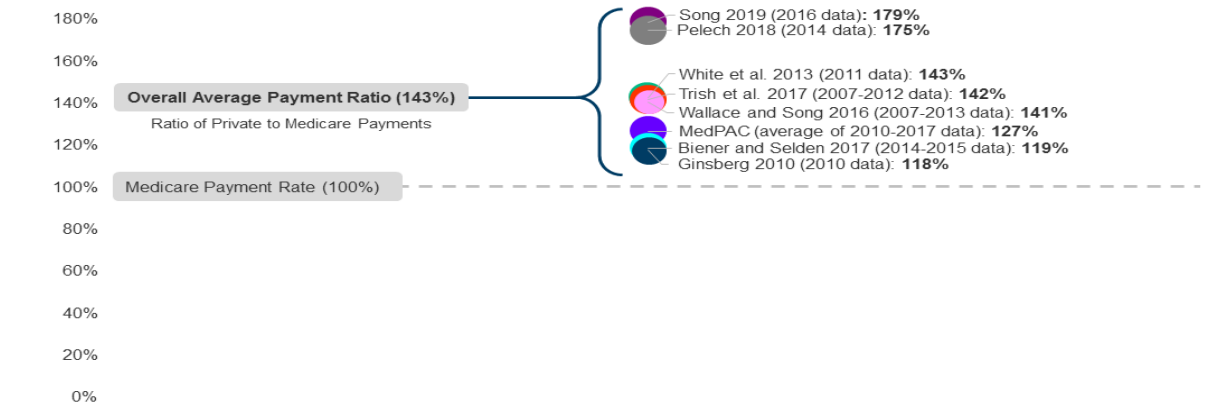
Interplay of Reimbursement Components
Introduction to Payment & Medicare Fee Schedules

- Medicare establishes fee schedules to reimburse physicians, facilities, and suppliers for services rendered
  - Medicare prices and maintains various fee schedules by setting of care
  - Depending on the setting of care, payment may also be fee-for-service or bundled (single payment for the entire episode of care)

Figure 5

Private Payment Rates for Physician Services Are 143% of Medicare Rates, On Average

Private Insurance Payment Rates for Physician Services as a Percentage of Medicare Rates, Studies Using 2010-2017 Data



SOURCE: KFF analysis of eight published studies of private-to-Medicare payment rates for physician services with data from the period 2010-2017.

KFF HENRY J KAISER FAMILY FOUNDATION

- In a recent analysis by Kaiser Family Foundation, private payer payment rates averaged 143% of Medicare rates overall (range 118%-179%); this number is 247% for hospitals
- Contrasting this upward trend, Medicaid payment rates have stayed relatively constant at ~70 to 90% that of Medicare

Summary of Medicare Telemedicine Services

Type of Service	What is the Service?	HCPCS/CPT Code	Patient Relationship with Provider
Medicare Telehealth Visits	A visit with a provider that uses telecommunication systems between a provider and patient.	Common telehealth services include: • 99201-99215 (Office or other outpatient visits • G0425-G0427 (Telehealth consultations, emergency department or initial inpatient) • G0406-g0408 (Follow-up inpatient telehealth consultations furnished to beneficiaries in hospitals or SNFs • https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes for complete list	For new* or established patients *To the extent the 1135 waiver requires an established relationship. HHS will not conduct audits to ensure that such a prior relationship existed for claims submitted during this public health emergency
Virtual Check-in	A brief (5-10 minutes) check in with your practitioner via telephone or other telecommunications device to decide whether an office visit or other service is needed. A remote evaluation of recorded video and/or images submitted by an established patient.	• HCPCS code G2012 • HCPCS code G2010	For established patients
E-Visits	A communication between a patient and their provider through an online patient portal.	• 99421 • 99422 • 99423 • G2061 • G2062 • G2063	For established patients

https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet; March 17, 2020