AdvaMed
Advanced Medical Technology Association

Reimbursement for Diagnostic Testing

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Introduction to ClearView Healthcare Partners

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- 15+ years experience with focus in diagnostics and medical devices
- Involved in launch of 100+ test products in cancer, diabetes, CV, and ID
- Prior leadership roles at Boston Healthcare Associates; experience in health policy on Capitol Hill
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About Clearview

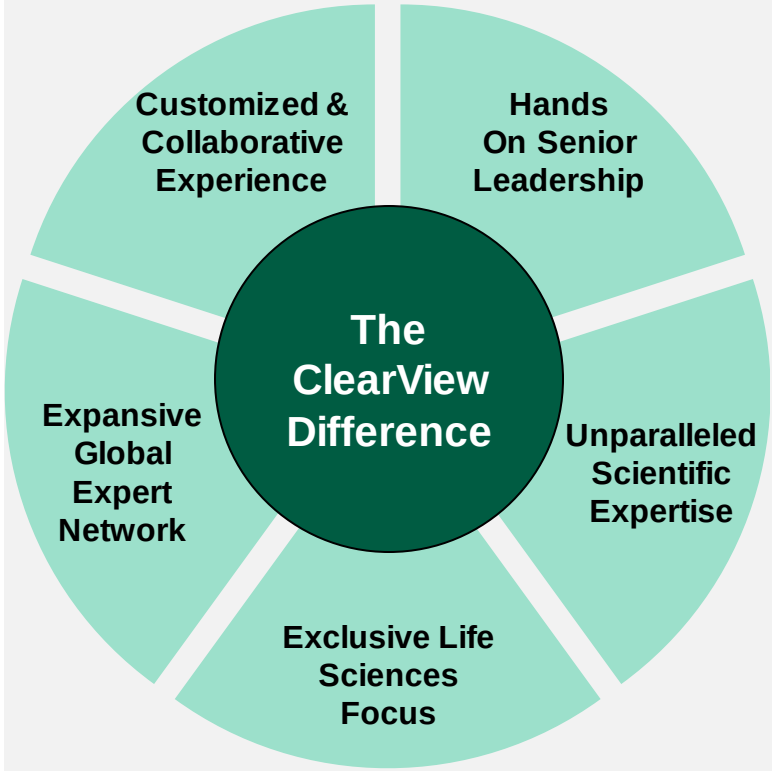
5 — **Offices** (Boston, New York, San Francisco, London, Zurich)

45+ — Members of **leadership team** dedicated to world class execution

325 — **Consultants** on professional staff relentlessly focused on projects

1500+ — Successfully executed **client engagements**

The ClearView Difference



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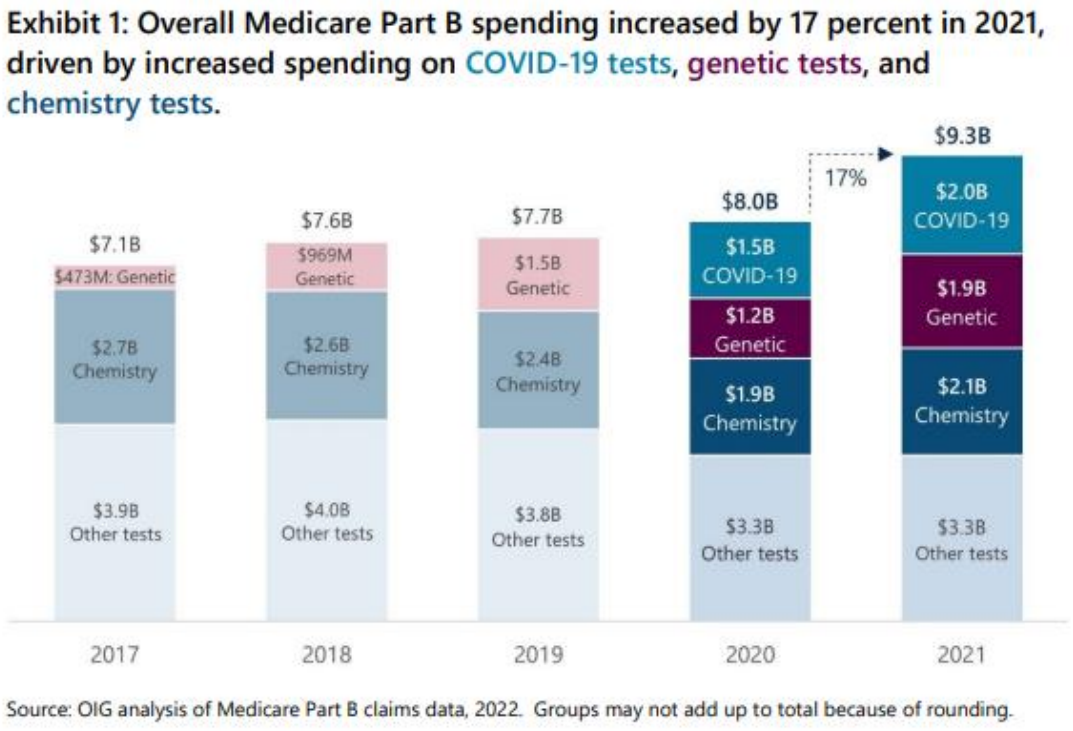
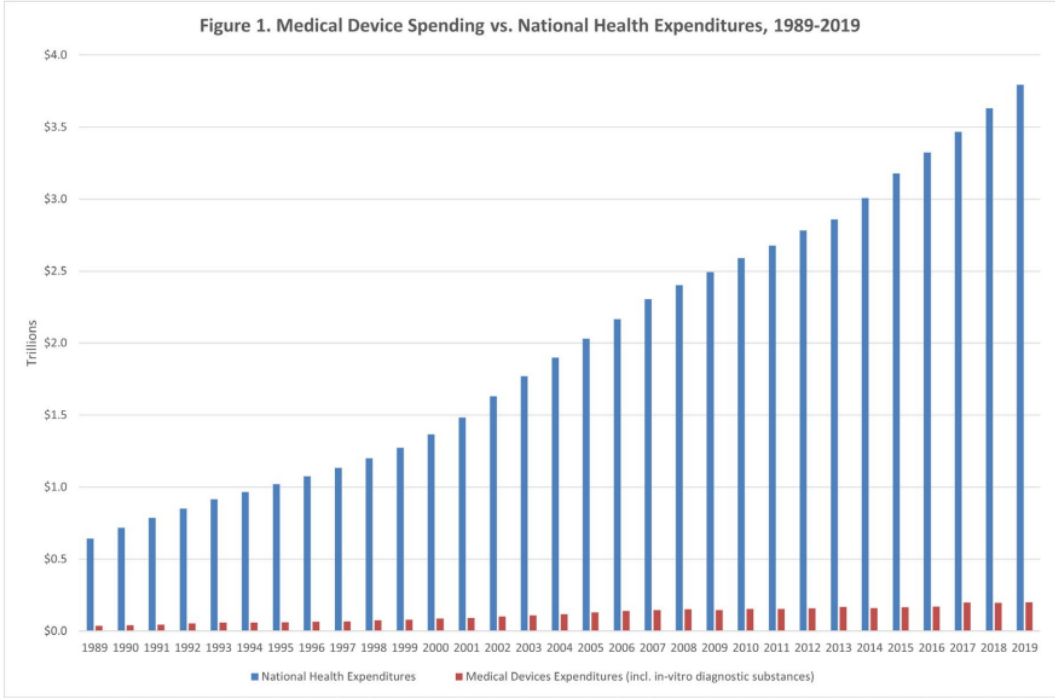
Since 2017 spending on testing services has continued to increase yet it is still only a fraction of the total cost of healthcare

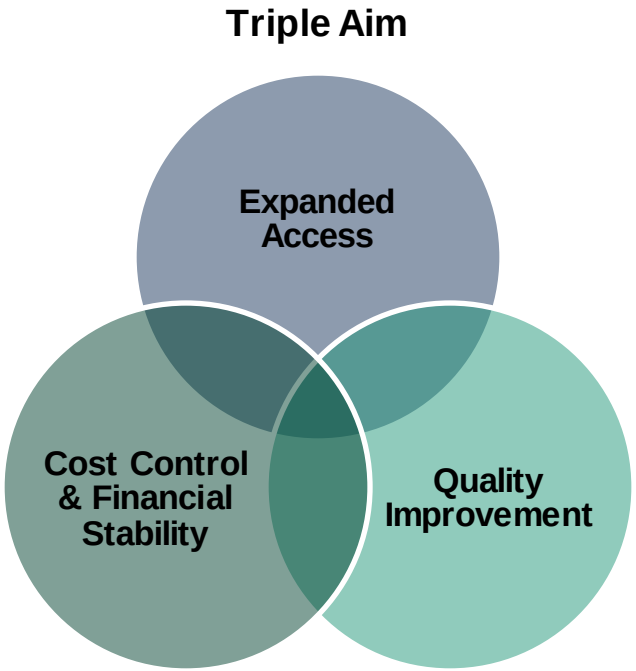
Medicare Spending on Testing Services 2021



Medicare Device Spending vs. National Health Expenditures 1989-2019 (including invitro diagnostics)



Health systems and reimbursement approaches are continually working towards balancing access, cost, and quality



Key Drivers of Healthcare Reforms

- Increasing health expenditures
- Relatively poor outcomes in key indicators
- Significant numbers of uninsured and underinsured
- Inefficiencies and variability in care and associated costs
- Impact of shifting demographics
- Payment structures that incentivizes overuse

The Patient Protection and Affordable Care Act (ACA) was designed to support this, but payment systems around the world reform and value seeking is an important trend both before and after the legislation

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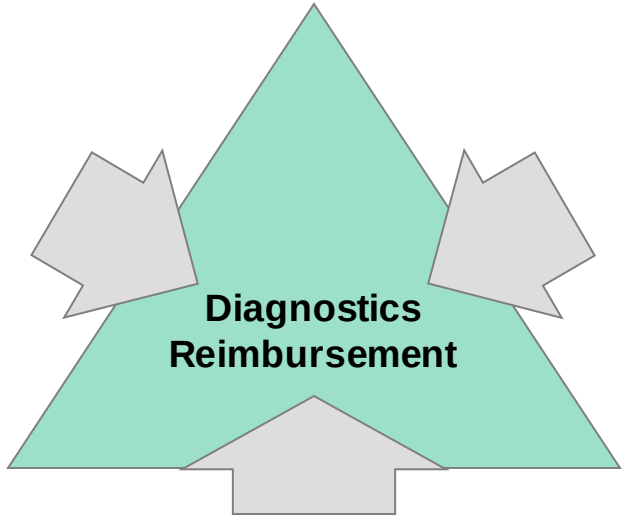
Source: ClearView Analysis

Reimbursement for a diagnostic services are based on coverage policies, available coding, and assigned payment rates

Core Components of Diagnostics Reimbursement

Coverage Policy

- **Is the test considered medically necessary or investigational/experimental?**
  - Many tests are implicitly covered without formal guidance by the payer



Coding

- **How the laboratory describes the test/laboratory procedure**
  - Laboratories use analyte-specific and non-specific codes depending on the method utilized

Payment System

- **Rates are associated with the code utilized to describe the service**
  - Rate may vary depending on payer type and whether the lab is an in-network provider

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Source: ClearView Analysis.

There are a few different diagnostic reimbursement strategies which depend on your desire to blaze a new trial towards differential reimbursement

Diagnostic Reimbursement Strategies

FEE SCHEDULE BASED, BELOW THE RADAR APPROACH

- Go "below the radar" by doing the following:
- Working within existing reimbursement framework as a low-profile test
- Using an existing code
- Securing payment rate relative to Medicare fee schedule rate
- Providing the test through a contracted lab

MINIMAL INVESTMENT OF RESOURCES

FEE SCHEDULE BASED, ABOVE THE RADAR APPROACH

- Some combination of the "below the radar" approach with the following elements:
- Creation of a new code
- Driving payer coverage
- Working to secure higher payment (cross-walking, gap-filling process, or RVU RUC analysis process for anatomic pathology tests)

WORKING TO ALTER REIMBURSEMENT ENVIRONMENT

VALUE BASED APPROACH

- Consider going "above the radar" by becoming a high-profile test that can do the following:
- Interest payers in explicit positive coverage
- Use a miscellaneous code
- Receive "value-based" premium payment (usually in 1000s of dollars)
- Often in sole-source lab

ACTIVE ENGAGEMENT

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Source: Boston Healthcare Associates

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Many tests benefit from implicit coverage though manufacturers may seek to alter or establish new guidance to secure explicit positive coverage

Coverage Environment Overview

Implicit Coverage

- Claims for test are reimbursed by payers even in the absence of a published policy
- Typically occurs by utilization of an established code with an associated payment rate that is not specific to that test

Allows payment under existing code or while more data is being generated

Positive Coverage

- Formal coverage policy outlines the benefits and uses of the test under which utilization will be reimbursed
- Explicit guidance is likely beneficial though may require substantial evidence of clinical benefit

Serves as a clear signal to physician community of test viability

Negative Coverage

- Medical technology group has explicitly reviewed the technology and determined it is not medically necessary
- Novel tests must then work to change coverage environment to gain reimbursement
- Negative guidance may not always be enforced

Requires provider to overcome existing negative coverage environment

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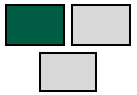
Source: ClearView Analysis.

Payer coverage decisions are influenced by both clinical and non-clinical factors, with the level of clinical evidence playing an increasingly key role



Drivers of Payer Coverage

Clinical Considerations	Political and Economic Considerations
Clinical Utility Evidence *What level of evidence exists to demonstrate the utility of a test?*	**Patient Advocacy / Political Pressure** *Is there public pressure to provide coverage/access to the test?*
Published Guidelines *Is use of the test explicitly supported by relevant guidelines?*	**Pricing / Health Economics** *Is there economic evidence to support cost savings / effectiveness?*
KOL Support *Do clinicians consider the test to be valuable?*	**Practice / Workflow Benefits** *Does this improve the way care is delivered?*

Coverage and Adoption

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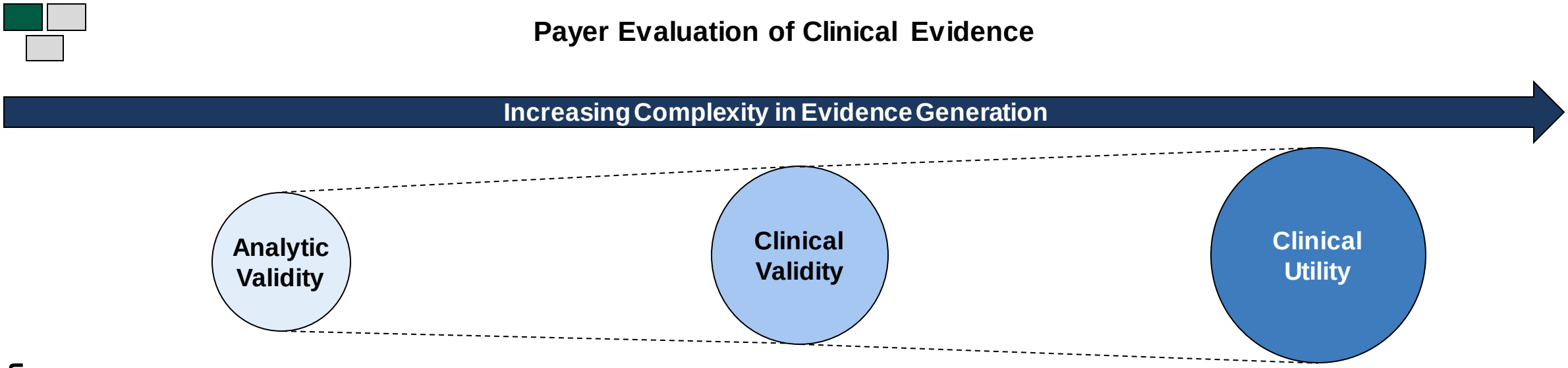
Source: ClearView Analysis.

Key: Focus of Next Slide

Evidence of clinical utility is the most convincing evidence class for payers but requires the most significant resources, time, and investment to develop



	Analytic Validity	Clinical Validity	Clinical Utility
Description	*How well the test predicts the presence or absence of a particular analyte*	*How well the analyte is related to the presence, absence, or risk of a specific disease*	*Ability to improve clinical outcomes through use of treatments conditional on test results*
Criteria	• Demonstration of analytic sensitivity and specificity • Additional documentation of quality control and assay robustness required	• Clear evidence discerning between patients with disease presence/high-risk and patients with disease absence/low-risk	• Evidence demonstrating enhanced clinical effectiveness, decreased serious adverse events, or significant impact on treatment decisions

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Source: ClearView Analysis.

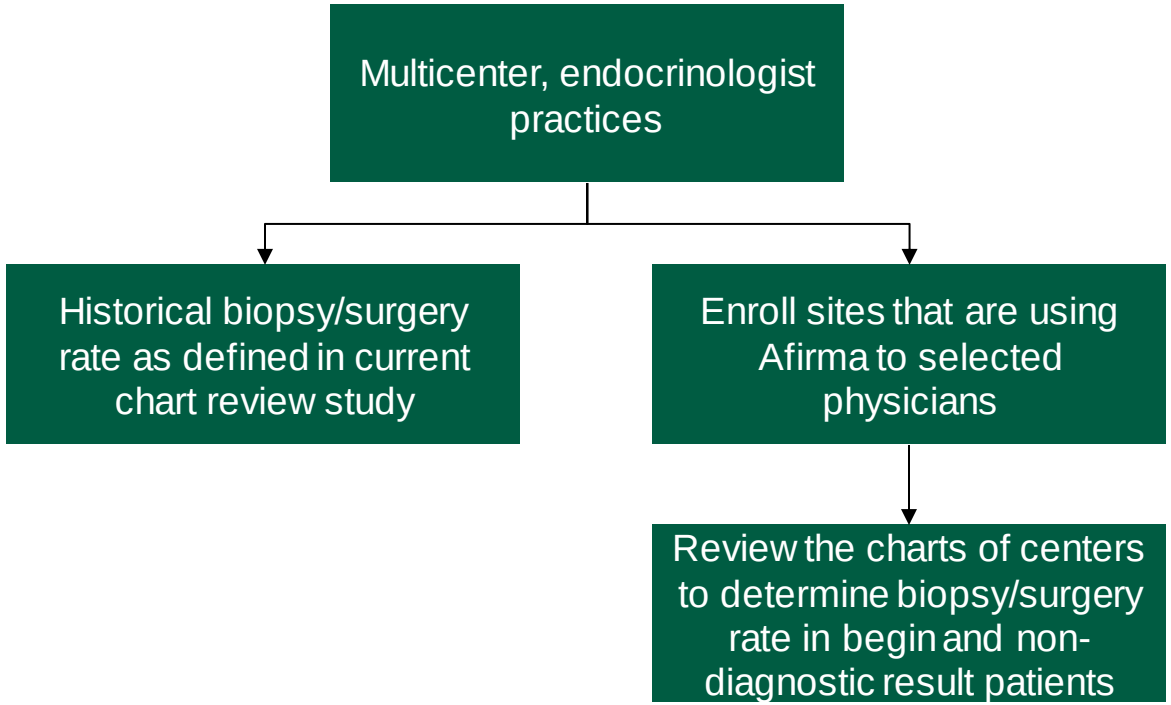
Veracyte used a comparison to a historical cohort to help define the clinical utility of its assay

Study Objective	*Determine how Afirma impacts the biopsy surgery rate as compared to institutions in which the test has not been introduced*

Study Components

- **Number of sites:** 21
- **Length of study:** 6 months
- **N:** 341 patients
- **Endpoints:**
  - Primary: Compare historical biopsy/surgery rate data with the biopsy/surgery rate in institutions where Afirma has been introduced
  - Secondary: Reason for recommendation to surgery
- **Results**
  - In cytologically indeterminate nodules, 7.6% of patients in the treatment group received surgery compared to 74% as stated in the literature

Trial Design



While FDA approval may be helpful in securing coverage, evidence requirements for payers it differs significantly from regulatory needs

Impact of FDA Approval on Payer Reimbursement

Regulatory Barrier	Reimbursement Barrier
• FDA assesses the safety and efficacy of a novel test through the PMA or 510K pathway • The FDA is the only stakeholder involved in the regulatory process • Cost is not considered	• Evidence showing test effectiveness and cost savings • Involves multiple stakeholders (1,200+ private payers, Medicare, Medicaid) • Cost is a key consideration
Several test technologies which were FDA approved still struggled to secure payer coverage (e.g., AlloMap, PLAC test, Pathwork tissue origin test)	Payers may say FDA approval is required, but in reality cover many tests which have not undergone FDA review (e.g., Down's Syndrome screening)

FDA approval is historically has only a modest impact on test coverage, as payers are focused on efficacy and cost while FDA is primarily concerned with safety and manufacturing

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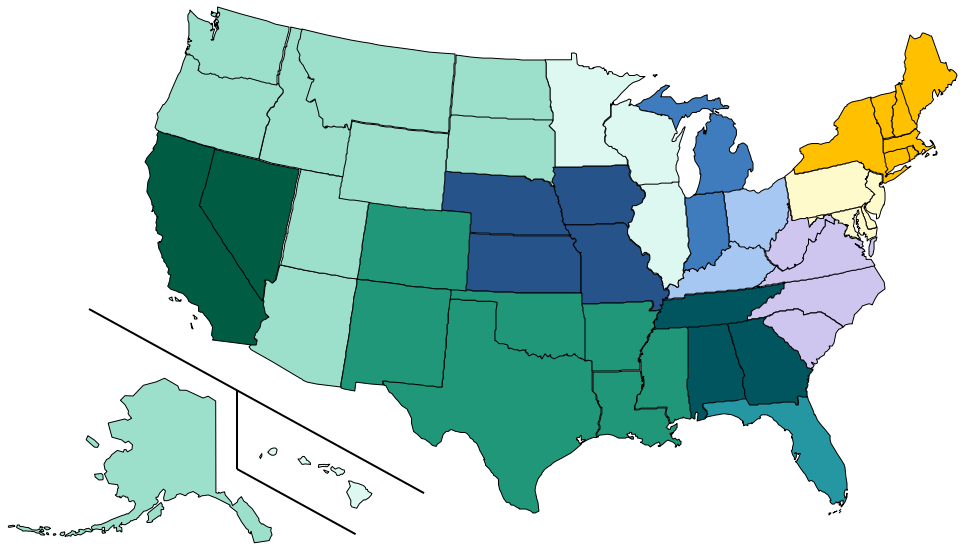
Source: ClearView Analysis.

Medicare Part B coverage of diagnostic tests may be determined nationally (NCD) or by individual MACs (LCD)

MAC Geographical Overview



JE Noridian	J5 WPS	JN FCSO
JH Novitas	J8 WPS	JK NGS
JF Noridian	J15 CGS	JL Novitas
J6 NGS	JJ Cahaba	JM Palmetto

Key Takeaways

- Medicare Administrative Contractors (MAC) are private companies responsible for administrating Medicare in their region
- Medicare coverage may be set either nationally via National Coverage Determinations (NCD), or at the MAC-level via Local Coverage Determinations (LCD)
  - NCDs generally require a longer, more complex review, often including a third-party evidence assessment (HRSA)
  - NCDs are all-or-nothing with respect to coverage of a particular service
- Coverage via LCDs require multiple engagements to ensure broad access, and can vary based on local needs

Medicare payment for diagnostic tests is based on the location of the lab where the test is performed

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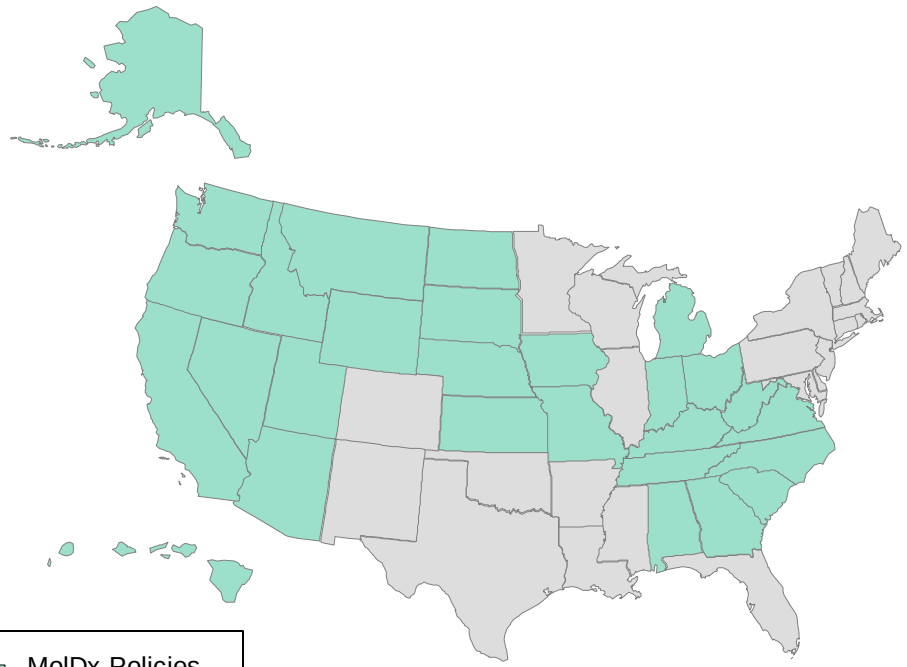
Source: CMS Documents; ClearView Analysis.

MolDx program establishes policy for molecular diagnostics coverage across 28 states on the basis of a technical evidence assessment

MolDx Program Overview



Key Takeaways

- MolDx was established by Palmetto GBA, a Medicare Administrative Contractor, to review advanced diagnostic technologies and define clinical utility requirements
  - Program evaluates diagnostics through a technical assessment and provides guidelines on the specific clinical utility criteria for molecular diagnostics
- Program determines the Medicare coverage and reimbursement policies for molecular diagnostics within its jurisdictions
  - Relevant jurisdictions include Palmetto GBA's jurisdiction M, Noridian jurisdictions E and F, CGS jurisdiction 15, and WPS jurisdictions 5 and 8

Robust clinical evidence can unlock favorable coverage decisions through key decision makers who increasingly look to create strict coverage policies in well-defined patient populations

Source: Palmetto GBA Website; ClearView Analysis.

Key Takeaways | Coverage

1. Product uptake is directly related to establishing payer coverage
2. Many tests can be successful with implicit coverage
3. Clinical utility is an increasingly key component of securing payer coverage
4. Securing MolDx coverage is a key tactic for establishing access to laboratory tests for Medicare patients

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Coding options and ability to utilize existing codes are often linked to test methodology

Coding Environment Overview

Methodology / Procedural Codes

- Available existing codes that describe procedures or steps rather than specific tests
- Associated with payment rates on fee schedule
- Examples include 83890 for molecular diagnostics, isolation, or extraction

Allows for payment with coverage review ("under the radar" approach)

Analyte-specific Codes

- A code that is to be used only by a certain test
- Often the result of years of work to secure code but sometimes readily available
- Can take form of a Category I CPT code such as, 86140 (C-reactive protein), or S-code S3835 (complete gene sequence analysis for cystic fibrosis)

Allows payer to track use of each specific test

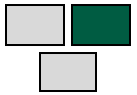
Miscellaneous Codes

- A code that will "kick-out" of the system for manual review by claims adjudicator
- No associated payment rate on fee schedule
- Example, CPT 84999, miscellaneous laboratory procedure

Ensures that payer will review claim

Source: ClearView Analysis.

Current Procedure Terminology (CPT) codes are a mixture of procedural and analyte descriptions depending on the particular test or utilized technology



Example Laboratory Codes

Code Types	Code Descriptions	Example Category I Codes	Example Description
Anatomic Pathology	• Describe analysis done by an MD pathologist • Paid on a physician fee schedule	88360	Morphometric analysis, tumor immunohistochemistry
Cytogenetics Codes	• Procedural steps and calls out a separate physician work component	88271	Molecular cytogenetics, DNA probe (e.g., FISH)
Molecular Diagnostics	• Historically coded as a procedure, current approach is to use analyte-specific codes for MDx	81210	BRAF, gene analysis
Infectious Disease MDx	• Specific to the tested disease first, with additional specificity to the method employed	87521	Hepatitis C, amplified probe technique
Immunoassay/ Chemistry	• Specific to what is being tested without mention of the specific method used	86140	C-reactive protein

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Source: CPT Codes; ClearView Analysis.

Key: Methodology Code | Analyte Code

Molecular tests may be described under a number of different code types, reflecting the complexity of diagnostic coding

Example Molecular Test Code Types

CPT Code Types	Code Descriptions	Example Code	Example Description
Miscellaneous (Category 1 Code)	• Non-specific code without assigned value, requiring individual claim processer review	**81599**	*Unlisted multianalyte assay with algorithmic analysis*
Molecular Pathology Tier 1 / 2 (Category 1 Code)	• Gene-specific codes for tests • Tier 1 is used for tests with "significant" volume, and Tier 2 for lower volume tests	**81275**	*KRAS gene analysis*
Genomic Sequencing Procedures (Category 1 Code)	• DNA or RNA sequence analysis methods that assay multiple genes or genetic regions relevant to a clinical situation	**81455**	*Targeted genomic sequencing panel, solid organ neoplasm*
MAAA (Category 1 Code)	• Typically lab-specific codes for panel tests using various types of analyses including an algorithmic component	**XXXXM**	*58 gene mRNA analysis with breast cancer risk algorithm*
Proprietary Laboratory Analyses (PLA code)	• Includes tests analyzing multiple DNA, RNA, or protein biomarkers and providing unique diagnostic information	**0037U**	*Sequencing, copy number, rearrangement, and TMB analysis, solid organ neoplasm*

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MAAA: Multianalyte Assays with Algorithmic Analyses; ADLT: Advanced Diagnostic Laboratory Test.
Source: CPT Codes; CMS Documents; ClearView Analysis.

Key: Pre-PAMA | Post-PAMA

Within the CPT code set, the Proprietary Lab Analyses (PLA) section includes both ADLTs and CDLTs as defined under PAMA

PLA CPT Code Overview

Description of PLA Codes

- Proprietary Laboratory Analyses (PLA) codes are a new addition to the CPT® code set approved by the AMA CPT® Editorial Panel
- They are alpha-numeric CPT codes with a corresponding descriptor for labs or manufacturers that want to more specifically identify their test
- Tests with PLA codes must be performed on human specimens and requested by the clinical laboratory or the manufacturer that offers the test

PLA Process

- In response to PAMA, the CPT Editorial Panel approved the new Proprietary Lab Analyses (PLA) section of the CPT code set in Q4 2015
- In addition, the panel approved the creation of the Proprietary Laboratory Analyses Technical Advisory Group (PLA-TAG)
- Codes are available 4 – 5 months after application

Eligible Tests

- The PLA code section includes Advanced Diagnostic Laboratory Tests (ADLTs) and Clinical Diagnostic Laboratory Tests (CDLTs) as defined under the Protecting Access to Medicare Act of 2014 (PAMA)
- These analyses may include a range of medical laboratory tests including Multianalyte Assays with Algorithmic Analyses (MAAA) and Genomic Sequencing Procedures (GSP)

PLA codes are now being used in lieu of a Category I codes to describe select sole-source or FDA-approved tests that labs or manufacturers wish to more specifically identify for reimbursement purposes

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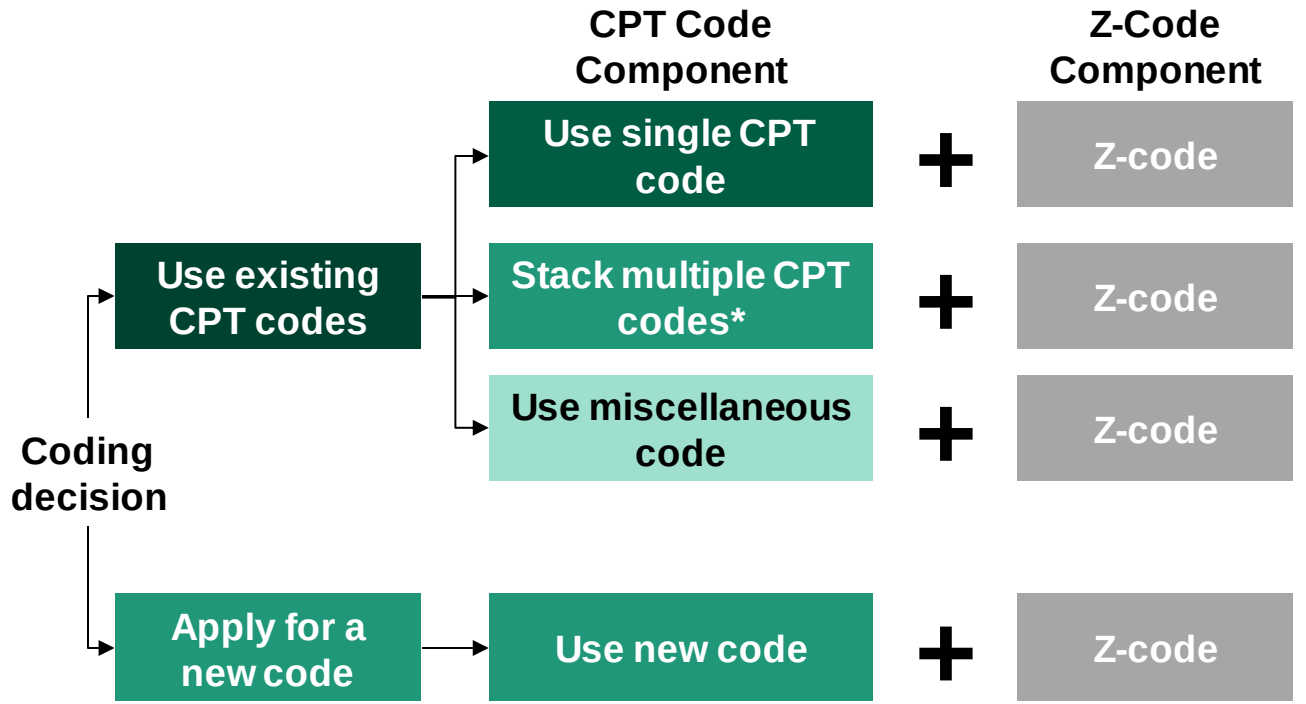
PLA: Proprietary Laboratory Analyses; ADLT: Advanced Diagnostic Laboratory Test; CDLT: Clinical Diagnostic Laboratory Test.
Source: ClearView Analysis.

MolDx coverage requires joint billing of a CPT code and a McKesson DEX Z code, which is used to identify tests described by non-specific CPT codes

Description and Considerations

- Z-codes are lab-specific unique identifiers assigned to diagnostic tests, and are **only used by MolDx**
- Z-codes are submitted **alongside the appropriate PLA/CPT code** for MolDx reimbursement
- Codes can be obtained within **2 weeks of application**
  - Application requires manufacturer to register the lab, and submitting test information
  - Obtaining a Z-code **does not impact coverage or code designation**
- Z-codes are **only necessary for submitting reimbursement through MolDx**

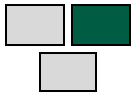
Coding Pathways For MolDx



**Note: CMS policy guidelines recommend against stacking multiple codes*

Source: MolDX Website; ClearView Analysis.

New codes may be needed if existing codes do not adequately describe the technology or reimbursement is not sufficient to support use



Considerations for Establishing New Codes

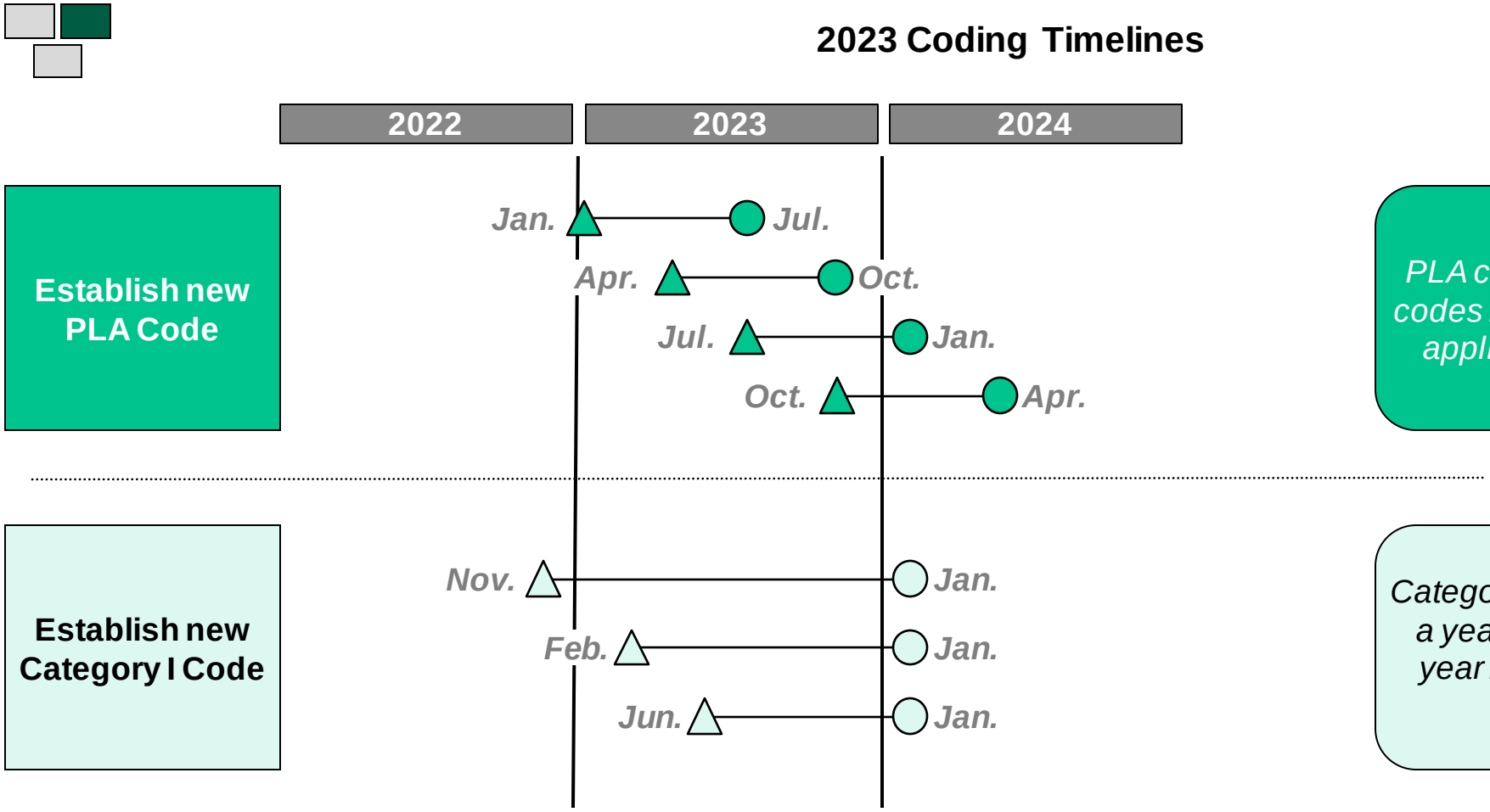
Current Payment Suffices	Existing Codes Describe Test: Yes	Existing Codes Describe Test: No
Yes	*Use existing codes*	*Use miscellaneous code or apply for a new code*
No	*Apply for a new code*	*Apply for a new code*

When new codes are needed, manufacturers must consider when best to obtain codes from a strategic perspective.

Establishing new coding before sufficient evidence exists to support positive payer coverage may create additional access challenges for customers, challenging long-term use

Source: ClearView Analysis.

The amount of time required to obtain a new code will vary based on the type of code being requested



PLA codes are released quarterly, and codes become effective ~6 months after application is submitted, if approved

Category I codes are only released once a year and, as such, may take over a year from application submissions to become effective

Source: AMA CPT Website; ClearView Analysis.

Key: △ Filing Deadline ○ Code Available for Use

Key Takeaways | Coding

1. Various types of CPT codes exist to describe molecular diagnostic tests
2. MolDx requires joint billing of a CPT code and a McKesson DEX Z-code
3. New coding should be considered if existing codes do not adequately describe the technology or are not reimbursed at amounts that reflect the value of the test
4. PLA codes require the least amount of time to obtain but may not have the same impact as a Category I CPT which may require over a year to obtain

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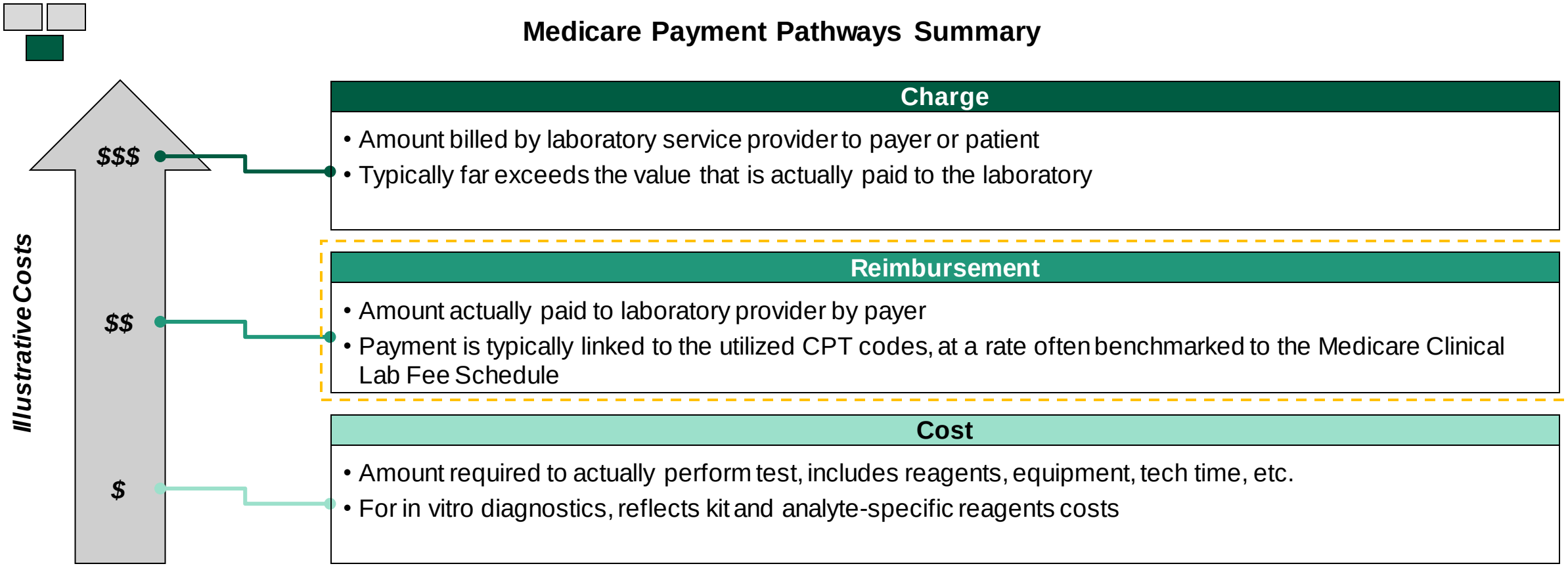
Outpatient reimbursement rates are based on the utilized CPT code, with commercial payers typically benchmarking to the published Medicare rates



Typically, outpatient tests are reimbursed separately, while inpatient diagnostics are often covered under a bundled reimbursement called a diagnostic related grouping system (DRG)

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Source: ClearView Analysis.

Key: Key Element

The reimbursed amount for a test will reflect payer assessment of pricing benchmarks, test methodology, expected use, and potential cost offsets

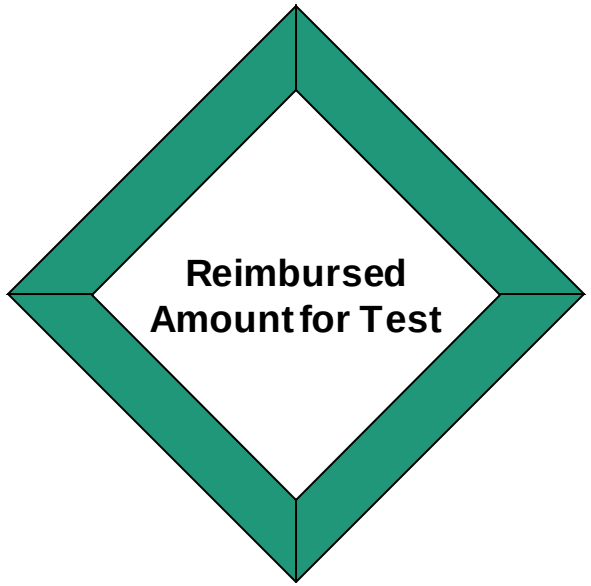
Determinants of Reimbursed Amount

Predicate Benchmarking

- **Payers will likely consider similar tests based on indicated use**
  - For example, a cancer test may be compared to HER-2/neu tests

Test Methodology

- **Reimbursed amount may also reflect the cost of performing the test, based on the employed methodology**
  - CPT coding may be used as an indicator



Anticipated Patient Volume

- **Degree of expected utilization may impact pricing, with commonly used tests expected to be lower in cost**
  - Conversely, targeted testing may enable higher prices

Health Economics Analysis

- **Potential to offset payer costs may be considered when assessing test value**
  - Overall cost benefits may support premium pricing

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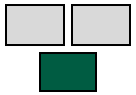
Source: ClearView Analysis.

Medicare test payment rates are publicly available and associated with either CLFS or MPFS for laboratory or physician services, respectively



Medicare Payment Pathways Summary

Test is primarily a physician service

Medicare Coverage of Test

Test is primarily a laboratory service

Medicare Physician Fee Schedule (MPFS)

- Tests with a significant interpretation component are viewed as physician services with a rate based on **time, materials, and physician expenses** required to execute the test
- Combined (global) value split into a professional component (PC or -26) for the physician's time and a technical component (TC)
- Rates are **reevaluated every 5 years** by the RVS Update Committee (RUS) and can **only be billed by a pathologist**

Clinical Laboratory Fee Schedule (CLFS)

- For existing tests, rates are based on the weighted median of private payer rates
- New tests can either be **cross-walked** where payment is linked to existing similar technologies, or **gap-filling,** where payment is based on MAC-determined local payment rates
  - For novel **advanced diagnostic laboratory tests (ADLTs)**, rates are based on list charges for the first 3 calendar quarters, after which payment is based on the weighted median of private payer rates

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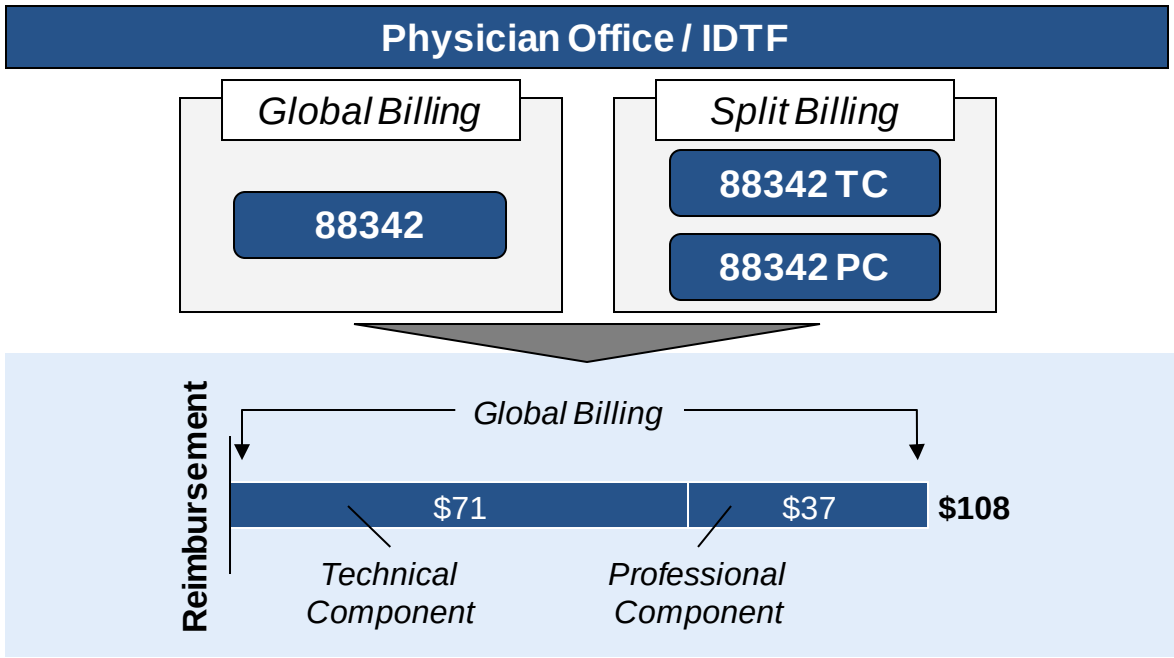
Source: CMS Documents; AMA Documents; ClearView Analysis.

Tests on the MPFS are reimbursed either at the total global cost or split between the facility and physician, depending on specific service provider

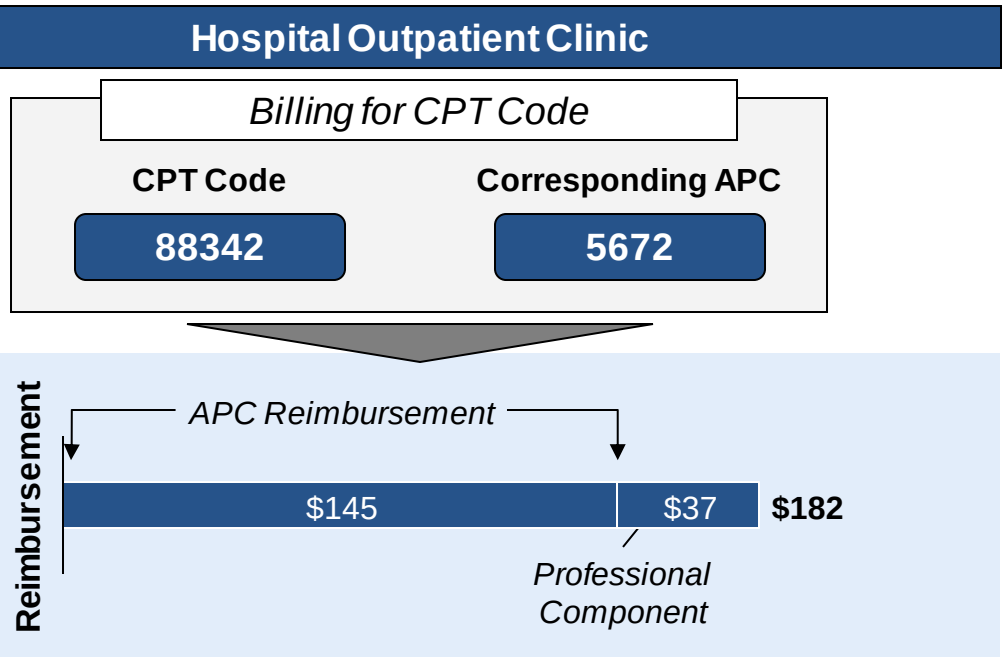
MPFS Payment Example

Physician Office / IDTF



- Offices / IDTFs may be reimbursed at **global billing rate if the practice is physician-owned**
- Otherwise, the **facility will bill the TC,** while the **interpreting physician bills the PC**

Hospital Outpatient Clinic



- Related CPT codes are **grouped under a single APC** code for **hospital outpatient setting**
- Medicare reimburses tests based on the **rate associated with the APC code**

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Source: CMS Documents; ClearView Analysis.

Key Takeaways | Reimbursement

1. Historically, commercial payers would benchmark to Medicare rates when determining reimbursement for CPT codes (e.g., 150% of Medicare)

2. Since PAMA, Medicare payment rates for existing tests are based on weighted medians of private payer rates

3. Medicare payment for new tests is based on either cross-walking (where benchmarks are available) or gap-filling

4. Tests that are described by unique CPT codes that cannot be used to describe other existing tests (e.g., sole-source, PLA, etc.) have better ability to control reimbursement by managing pricing as compared to tests that share CPT codes

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Several key trends have emerged that may impact how manufacturers think about developing and commercializing molecular diagnostic tests

Select Trends Impacting Molecular Diagnostics

- COVID Impact
- Balancing test regulation and quality control
- Implementation of SALSA to reform PAMA
- Increasing number and significance of technological innovations

Some belief that COVID might change payer perceptions of the value of testing and increase support for point-of-care and at-home testing

Lasting Impact of COVID?

Public Health Emergency Mandates

- Payers were required to cover COVID testing and provide payment for novel CPT codes for testing
- Many of those requirements will drop once the PHE ends in May 2023

"Because of the public health emergency, we were forced to pay regardless if we thought it was beneficial or not."

Over-the-counter Testing

- COVID has caused a shift in perspectives around payment for at-home and/or consumer testing
- There may be some lasting impacts on payer willingness to pay for testing in non-traditional settings of care

"OTC tests were only useful during the PHE when COVID was very contagious to inform pts, reducing spread."

Altered Regulatory Approaches

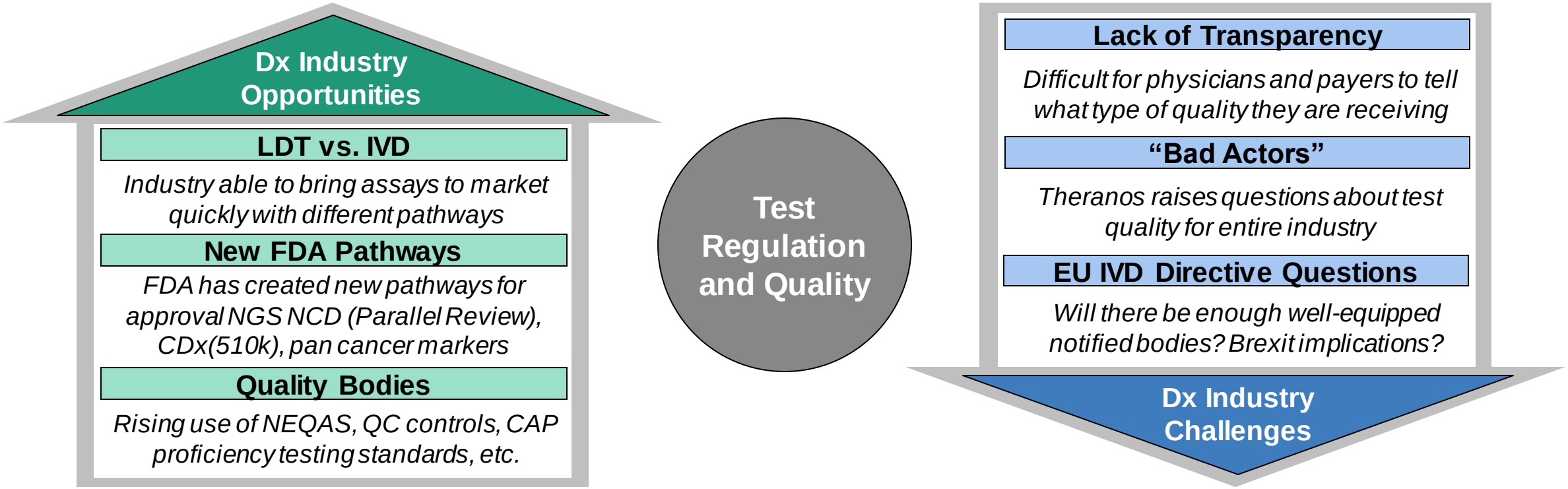
- Many COVID assays were approved in record time through "Emergency Use Authorization" pathway
- Some regulatory experts suggest this will change approval approaches moving forward

"I know these tests are not FDA approved but they have still been validated."

Source: ClearView Analysis.

The industry continues to try to balance test availability with adequate regulation/quality

Changing Balance between Test Regulation and Quality



Laboratorians recognize a need for better quality, but it is unlikely to come until payers begin to require demonstrations of quality as a condition for payment

ClearView Healthcare Partners AdvaMed Advanced Medical Technology Association

Source: ClearView Analysis.

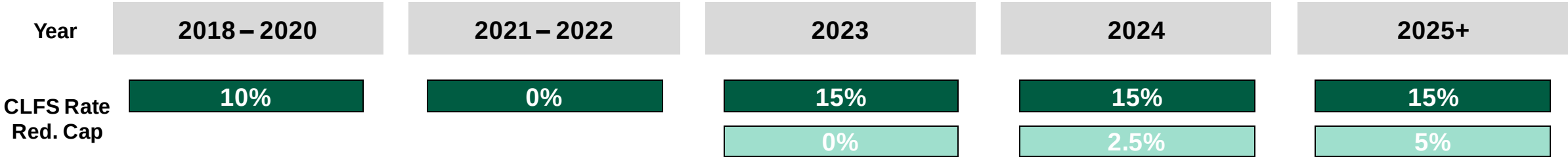
The SALSA Act was introduced in June 2022 to reform PAMA and lower the Medicare CLFS rate reduction cap to be sustainable at 5% from 2025 onwards

PAMA

- In 2014, Congress passed the Protecting Access to Medicare Act (PAMA), which led to significant changes to the mechanism by which Medicare assigns payment rates to laboratory tests that are not ADLTs
- PAMA established that the Medicare payment amount for a test on the CLFS will generally be based off a weighted median of private payer rates for that test
- Reimbursement rates for clinical laboratory services have been and continue to be on a **course of multi-year, double-digit cuts** (10 – 15% per year)[1]

SALSA

- Saving Access to Laboratory Service Act (SALSA) is a new legislation that seeks to modify PAMA requirements
  - SALSA places emphasis on more accurate and representative data collection from all laboratory market segments (outside of just large commercial labs) to determine clinical test rates and set a sustainable path forward
- Annual limits will be set on CLFS payment rate reductions and increases, which **lowers the cap on annual rate reductions to 5% in 2025+**

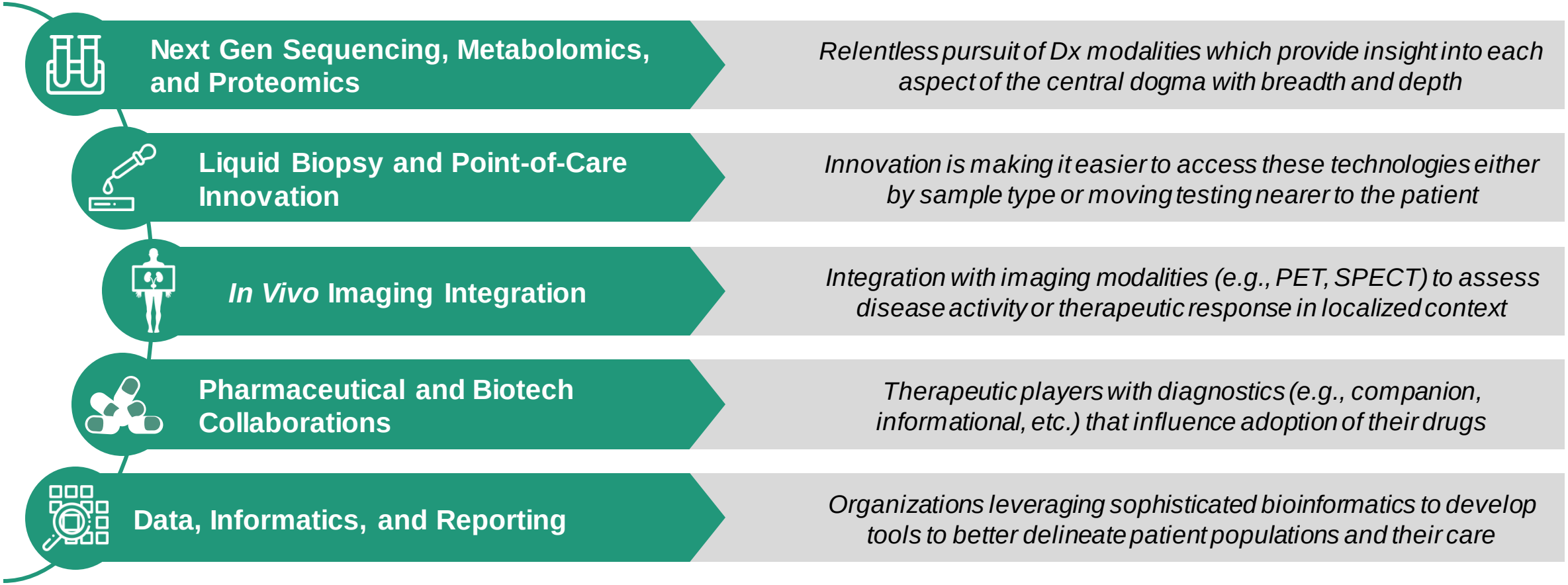


ClearView Healthcare Partners | AdvaMed Advanced Medical Technology Association

[1]No changes to reimbursement rates during COVID-19 public health emergency. ADLT: Advanced Diagnostic Laboratory Test; CLFS: Clinical Lab Fee Schedule; PAMA: Protecting Access to Medicare Act; SALSA: Saving Access to Laboratory Service Act. Source: CMS Website; ACLA Website; ClearView Analysis.

Exciting technology developments are occurring but there are many questions about how to incorporate them into community based clinical care

Overview of Select Technological Developments



Source: ClearView Analysis.

Q&A

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AppliedVR

The Leading Provider of Immersive Therapeutics (ITx).

April 2023

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THE CHALLENGE

Chronic Pain Epidemic Driven by Outdated Care Paradigm and Lack of Coverage.

DTx faces inherent challenges in addressing epidemic.

CHRONIC PAIN EPIDEMIC…

Size & Cost of Pain Epidemic

100m

$800b

U.S. patients & annual cost of opioids, Injectable & procedures

Major Gap in Access to Care

1 provider per

30k-60K

Current guidelines call for integrated pain care, but US lacks capacity to deliver

ACCESS BARRIER

…THAT DTx is Challenged to SOLVE:

1. SaMD means **no CMS** Coverage Category
2. Need for investment in **clinical and econ data**
3. **No** clear entry point
4. Low **adherence rates**

Privileged and Confidential.

RELIEVRx™ PROGRAM

The First and Only Prescription

VR Device for Chronic Lower Back Pain.

Clinically proven to be
Engaging, Easy to Use and Efficacious

FDA-authorzed De Novo Class II VR device
(hardware / software combo = SiMD)

CMS Code (E1905) Virtual Reality (VR) Cognitive Behavioral Therapy (CBT) device, including pre-programmed therapy software

INDICATED FOR:

- Adjunctive treatment
- In-home use
- Cognitive & behavioral therapy skills
- Patients 18+ with CLBP

CASE STUDY

DME Benefit Category: HCPCS Coding

The DME Benefit category is defined in statute at 42 CFR §414.202:

- Can withstand repeated use.

- Has an expected life of at least 3 years.

- Is primarily and customarily used to serve a medical purpose.

- Generally is not useful to an individual in the absence of an illness or injury.

- Is appropriate for use in the home.

LEARN FROM ANALOGS

Learn From Previous Decisions: A9291

- Establish new HCPCS Level II code A9291, “Prescription digital behavioral therapy, fda cleared, per course of treatment” CMS believes that establishing a code at this time may facilitate options for non-Medicare payers to provide access to this therapy in the home setting.
- No Benefit Category
- No Payment

Pear Therapeutics - HCP21090135K6E, HCP210902RNB7C, HCP2109034KYG9
https://www.cms.gov/files/document/2022-hcpcs-application-summary-biannual-1-2022-non-drug-and-non-biological-items-and-services.pdf (page 88)

- Revise existing HCPCS Level II code A9291, “Prescription digital behavioral therapy, fda cleared, per course of treatment” to now read “Prescription digital cognitive and/or behavioral therapy, fda cleared, per course of treatment.” CMS believes that HCPCS Level II code A9291, as revised, describes **EndeavorRx®**.

EndeavorRx® - HCP220103YXJ32
https://www.cms.gov/files/document/2022-hcpcs-application-summary-biannual-1-2022-non-drug-and-non-biological-items-and-services.pdf (page 136)

DME Definitions: A9291

- No Medicare DMEPOS benefit category. We continue to believe these products fall **outside the definition of DME.** The durable medical equipment benefit is for equipment such as a wheelchair, hospital bed, ventilator, or oxygen concentrator rented to a patient for use in their home.

  Software that is run on computers would not work unless the patient also has a smartphone, computer or another type of durable device that would enable use of the software. **Smartphones and computers are generally useful to individuals in the absence of illness or injury and are therefore not DME**. Without the computer, the software would not work.

  Digital therapies or computer software are housed on non-medical devices like smartphones or computers and the equipment and software as a whole are not DME. Whether or not the item could fall under some other Medicare benefit category can be considered, but would not be addressed under the DMEPOS BCD process.

  Pear Therapeutics - HCP21090135K6E, HCP210902RNB7C, HCP2109034KYG9
  https://www.cms.gov/files/document/2022-hcpcs-application-summary-biannual-1-2022-non-drug-and-non-biological-items-and-services.pdf (page 88)

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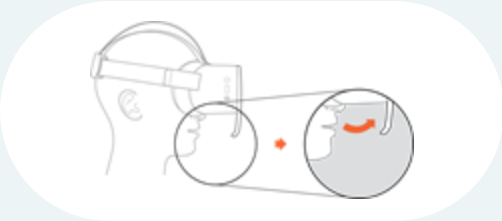
Comprehensive Strategy:
Regulatory and Reimbursement

What went well for the RelieVRx program?



- SiMD - kiosk the software on the modified hardware and ensure no non-medical use is possible.
  - Gaze-based navigation, patented breathing amplifier

ANSI American National Standards Institute

- Testing to home medical equipment standards: ISO/ANSI 60601 testing

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=43309

FDA U.S. FOOD & DRUG ADMINISTRATION

- Clinical evidence: de novo authorization based on RCT data
  - Breakthrough device designation
  - Ongoing clinical evidence commitment

- Special controls for Class II Medical Device
  (listed on next slide)

Sec. 890.5800: Virtual Reality Behavioral Therapy Device

(a) ***Identification.*** A virtual reality behavioral therapy device for pain relief is a device intended to provide behavioral therapy for patients with pain. Therapy is administered via a virtual reality display that utilizes a software program containing the behavioral therapy content.

(b) ***Classification.*** Class II (special controls). The special controls for this device are:

(1) Clinical performance testing under the labeled conditions for use must validate the model of behavioral therapy as implemented by the device and evaluate all adverse events.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Software verification, validation, and hazard analysis must be performed.

(4) Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.

(5) Labeling must include the following:

(i) A warning regarding the risk of nausea and motion sickness;

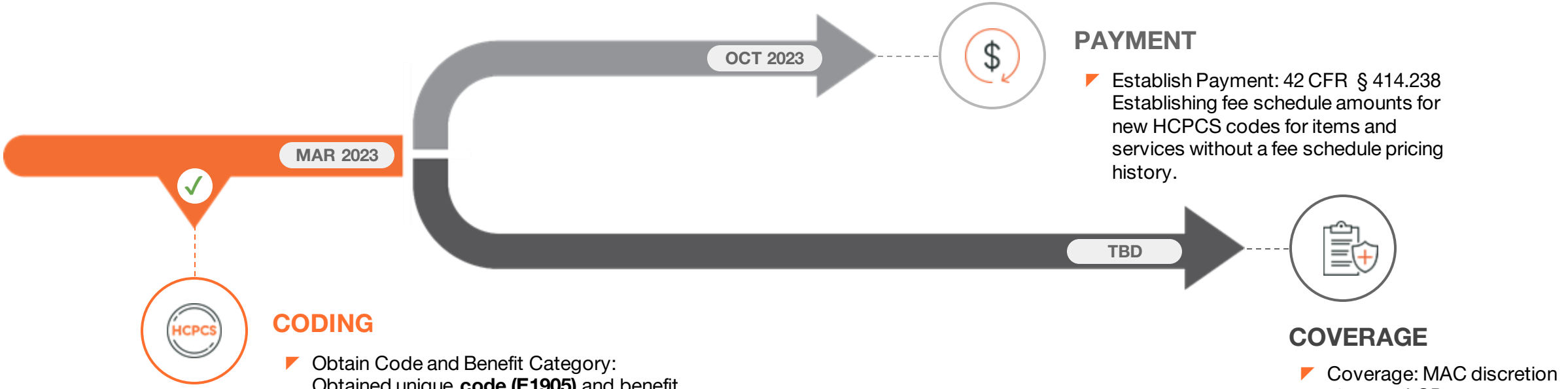
(ii) A warning regarding the risk of discomfort from the device; and

(iii) A summary of the clinical testing with the device.

[88 FR 985, Jan. 6, 2023] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=890.5800

Clear CMS Pathway Solves #1 Impediment Facing DTx - Scaled Reimbursement.

CMS pathway legitimizes and accelerates commercial adoption.



CODING

- Obtain Code and Benefit Category: Obtained unique **code (E1905)** and benefit category (DME).
- Navigating the constraint for DTx.

PAYMENT

- Establish Payment: 42 CFR § 414.238 Establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history.

COVERAGE

- Coverage: MAC discretion absent a LCD

Thank you.

Incorporating Patient Preferences into Coverage and Payment Decision Making

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Align. Achieve. Accelerate.

Introductions

Barry Liden
Director, Public Policy, USC Schaeffer Center for Health Policy & Economics
Former Vice President, Patient Engagement – Edwards Lifesciences
Former Chair, MDIC Science of Patient Input & Patient Preferences Research Working Groups

Harry Kotlarz
Assistant VP, Medical Device Innovation Consortium (MDIC)
30 year background in health economics, market access, outcomes research and reimbursement in Medtech

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Goals

1. Understand what are patient preferences
2. Learn how patient preferences can be incorporated into coverage and payment decision-making
3. Understand the potential challenges and limitations to patient preferences

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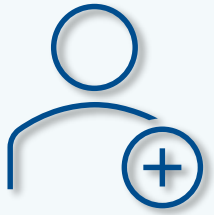
Why Patient Preferences Should Be Considered



Patients have a right to participate in decisions impacting them

Decision making will be more informed as patients hold experiential knowledge on their disease

Involving patients provides social legitimacy to decisions

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Why Patient Preferences Should Be Considered

Manufacturers improve their products

Patients get access to new products faster

Regulators and payers prioritize treatments that bring more value to society

Physicians and patients make better decisions about what the right treatment is

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Wait, what are "Preferences" again?

Evidence representative of a group

Often obtained from surveys

Characteristics or features

"Qualitative or quantitative statements of the relative desirability or acceptability of attributes that differ among alternative interventions."

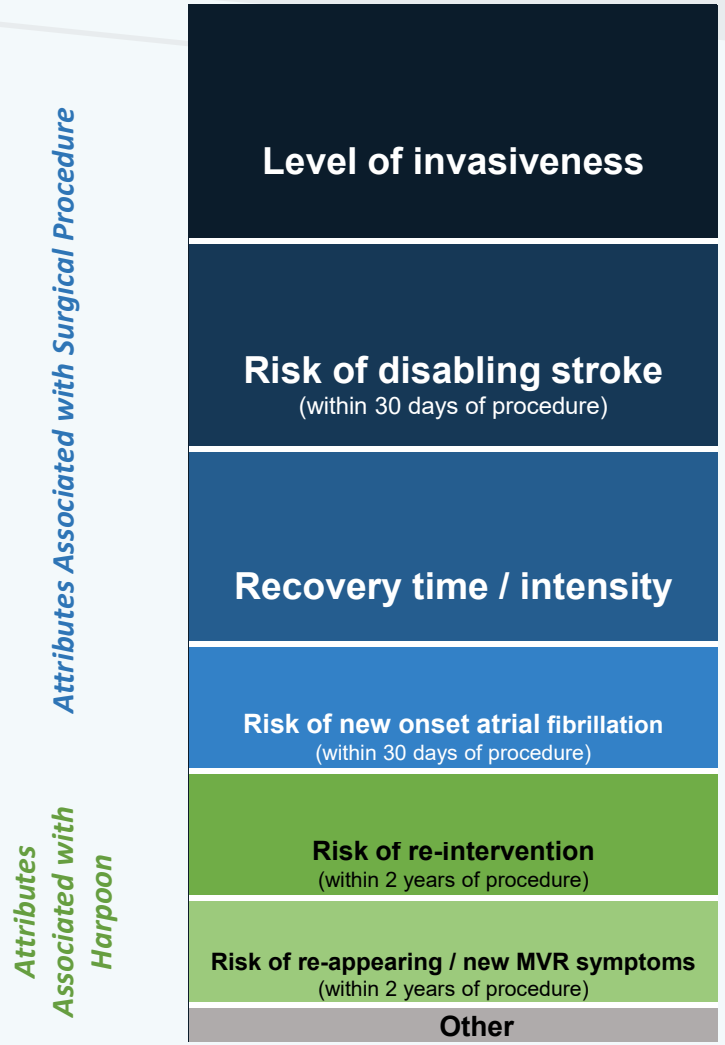
Source: CDRH

Defined by what people are willing to give up

or

- health states
- care processes
- health policies
- other

Relative weight of high-level factors on decision to undergo a procedure to repair / replace mitral valve



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Source: Janssen E, Keuffel EL, Liden B, Hanna A, Rizzo JA. Patient preferences for mitral valve regurgitation treatment: a discrete choice experiment. Postgrad Med. 2022 Mar;134(2):125-142. doi: 10.1080/00325481.2021.2020571. Epub 2022 Jan 11. PMID: 34981982.

slido

What are patient preferences?

ⓘ Start presenting to display the poll results on this slide.

What is the Difference Between PPI and PROs?

Patient Preference Information (PPI)

Qualitative or quantitative assessments of the relative **desirability or acceptability** to patients of specified alternatives or choices among outcomes or other attributes that differ among alternative health interventions.

PPI is an assessment of desirability or acceptability (what a patient wants).

Patient Reported Outcomes (PRO)

Any report of the **status of a patient's health condition** that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.

PRO is a measure of a **realized outcome** (what it is or what it is like).

Tradeoffs:

How much it matters and what tradeoffs are patients willing to make.

Quantitative methods designed to capture trade-off information.

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MDIC Patient Centered Benefit-Risk (PCBR) Framework

Background
Completed in response to 2012 FDA guidance that highlighted the importance of patient-centric measures in regulatory benefit-risk assessments

Scope
A framework was developed to help the FDA and industry sponsors understand how patient preferences regarding benefit and risk might be integrated into the review of innovative medical devices

Methods
Public-private partnership of experts from medical device industry, government, academia and non-profits collaborated on development of the MDIC patient centered benefit-risk framework (PCBR)

Results
The MDIC Framework examines what patient preference information is and the potential use and value of patient preference information in the regulatory process and across the product development life cycle

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MDIC Science of Patient Input (SPI)

Science of Patient Input Resources:

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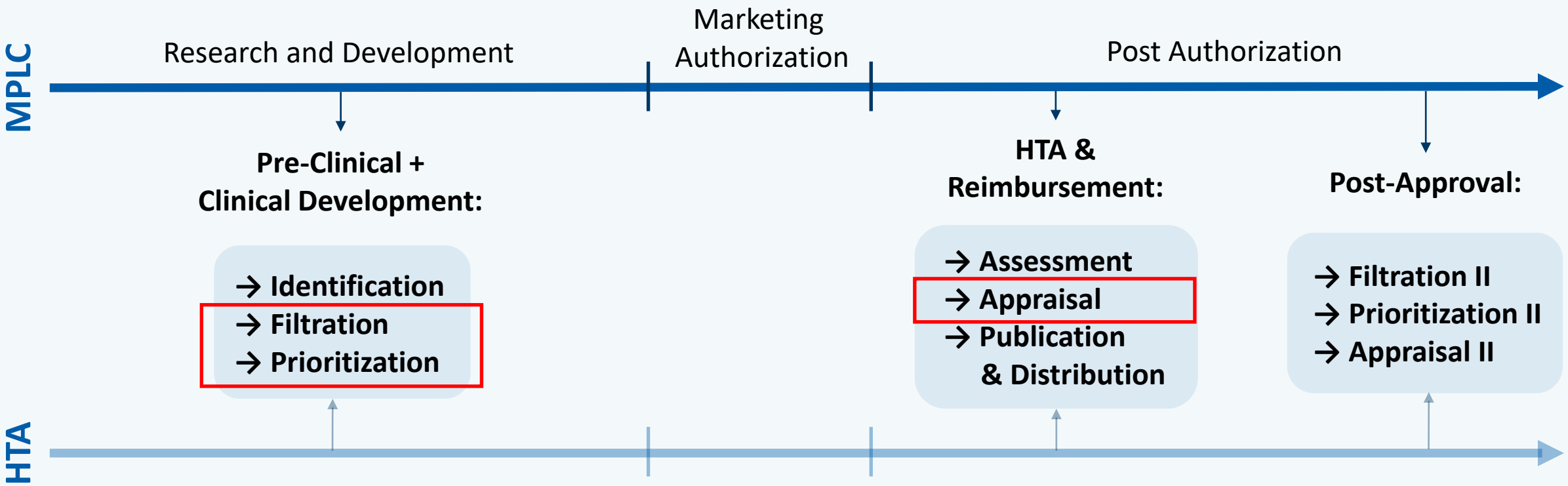
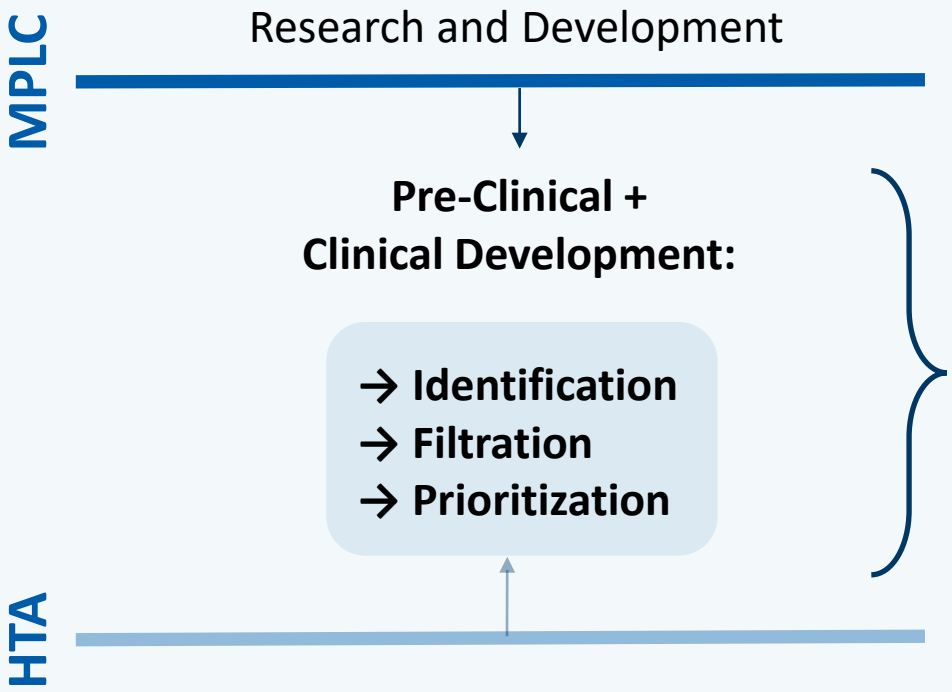
Opportunities to Use PPI in HTA



MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

Whichello C, Bywall KS, Mauer J, Stephen W, Cleemput I, Pinto CA, et al. An overview of critical decision-points in the medical product lifecycle: Where to include patient preference information in the decision-making process? Health Policy. 2020 Dec 1;124(12):1325–32.

Opportunities to Use PPI in HTA "Development"



HTA "Scoping"

→ Deciding which technologies to assess relative to other therapies

→ Deciding prioritization of HTA agenda

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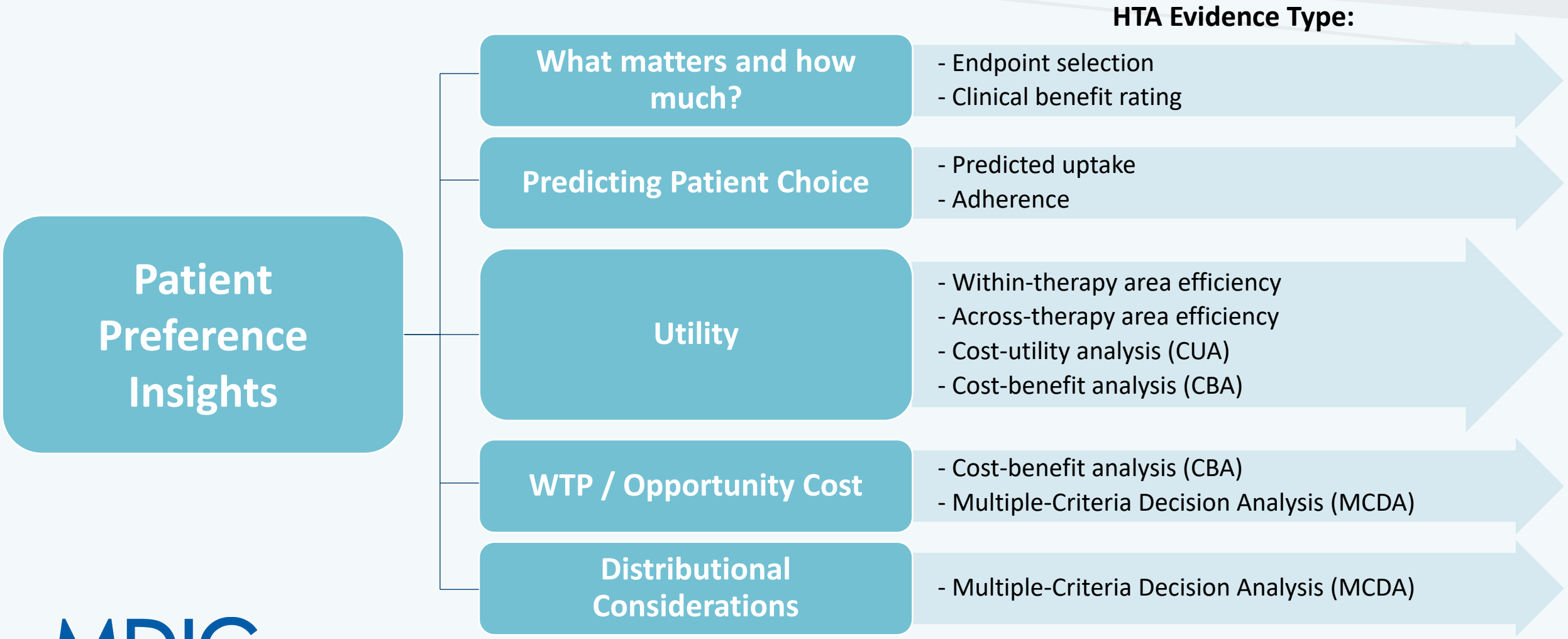
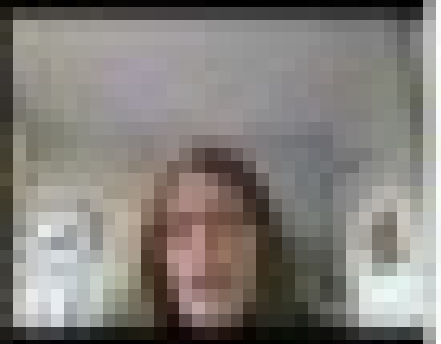
Opportunities to Use PPI in HTA Appraisal



MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

Marsh, K., De Bekker-Grob, E., Cook, N., Collacott, H., & Danyliv, A. (2021). How to integrate evidence from patient preference studies into health technology assessment: A critical review and recommendations. *International Journal of Technology Assessment in Health Care, 37*(1), E75. doi:10.1017/S0266462321000490

Example of PPI in HTA: TAVR in Canada



Patients valued...

Example of Patient Preferences: Coverage

Shared Decision Making

Coverage with Evidence Development

Prioritization of outcomes for evidence development

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Challenges and Limitations of Patient Preference Information

A **knowledge gap** regarding what does and does not comprise Patient Preferences

Weighting and impact by HTAs and Payers **varies and lack of transparency**

Sample size, recruitment strategy – finding the right patients

Limitation of qualified vendors (experience and options), demonstrating ROI internally to secure funding

Key stakeholders in U.S. payer community who understand the meaning and role of PPI are **not vigorously requesting it**

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MDIC's Work in Patient Preferences – Health Economics and Patient Value (HEPV)

Sept 2022:

AHRQ issued a draft report on ways that Coverage with Evidence Development (CED) rules might be edited and updated.

Feb 2023:

CMS convened a panel of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) to examine and update the requirements for clinical studies submitted for CMS coverage under CED

Current:

TCET Proposed Rule Pending

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FDA Published Studies and Ongoing Projects

FDA scientists frequently collaborate with a variety of stakeholders to conduct PPI studies to inform clinical trial design and medical device regulatory decision making.

Examples include medical devices for:

- Obesity
- Parkinson's Disease
- Amputation
- Glaucoma
- Uterine Fibroids
- Prostate Cancer
- Chronic Pain
- Adolescent Scoliosis
- Heart Failure
- Kidney Disease

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Patient Preferences Are:

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Rank the most likely acceptable uses of patient preferences by payers?

ⓘ Start presenting to display the poll results on this slide.

Thank You For Your Attention

Barry Liden
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Harry Kotlarz
hkotlarz@mdic.org

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Trends in Commercial Health Insurance

Robert C. McDonald, MD, MBA
President, Aledo Consulting
April 25, 2023, 2:40 – 3:30 PM
AdvaMed: Medtech Coverage, Coding, and Reimbursement 201 Workshop

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Agenda

- **The Single Most Important Trend**
- **Structure of US Insurance Markets**
- **Structure of Commercial Insurance**
- **Considerations for MedTech Companies**
- **Emerging Trends in Commercial Insurance Coverage**
- **Conclusions**

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The Single Most Important Trend

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The Single Most Important Trend

Payment for Healthcare Products and Services Reflects Society's Values and Is In Constant Evolution.

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The Single Most Important Trend

How Long Have non-Medicare Reimbursement Rules Existed?

When were the first medical technology reimbursement rules published?

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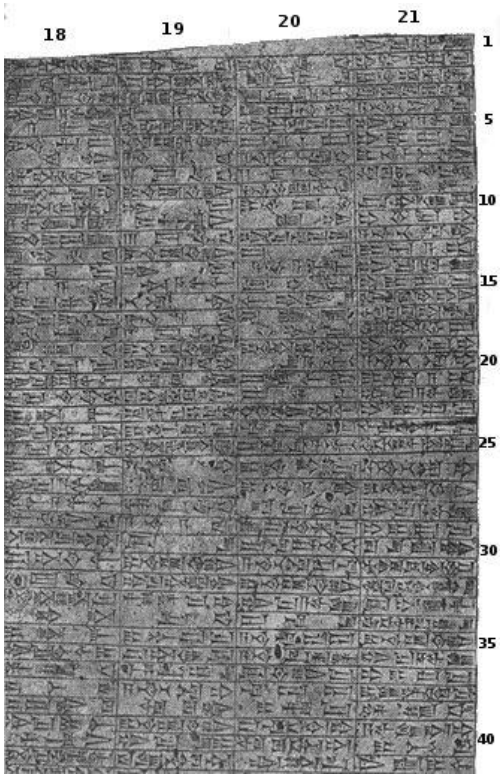
The Single Most Important Trend

Code of Hammurabi 1760 B.C.



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Code of Hammurabi 1760 B.C.

Approximately 260 rules that served as law in ancient Babylon

- Nine of these (215-223) pertained to physician treatments
  - If a physician makes a large incision with an operating knife and cures it, or if he open a tumor (over the eye) with an operating knife, and saves the eye, he shall receive ten shekels in money.
  - If the patient be a freed man, he receives five shekels.
  - If he be the slave of some one, his owner shall give the physician two shekels.
  - If a physician makes a large incision with the operating knife, and kills him, or open a tumor with the operating knife, and cut out the eye, his hands shall be cut off.
  - If a physician makes a large incision in the slave of a freed man, and kills him, he shall replace the slave with another slave.
  - If he had opened a tumor with the operating knife, and put out his eye, he shall pay half his value.
  - If a physician heals the broken bone or diseased soft part of a man, the patient shall pay the physician five shekels in money.
  - If he were a freed man he shall pay three shekels.
  - If he were a slave his owner shall pay the physician two shekels.

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Code of Hammurabi 1760 B.C.

Paying for healthcare services is an ancient and universal undertaking:

- First fee table
- Inequity among specialties (procedural and non-procedural) is about 3,800 years old
- First “global payment” approach - payment is one check for entire service (no facility/professional split)
- First payment differential depending upon patient characteristics
- First malpractice insurance -- different consequences for successful/unsuccessful outcome

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Payment for Healthcare Products and Services Reflects Society's Values and Is in Constant Evolution

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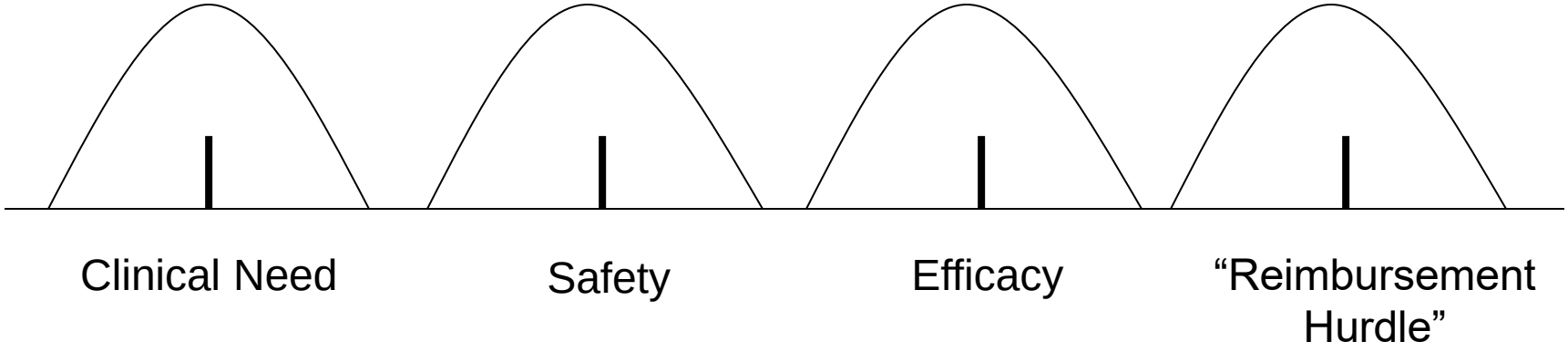
All Four Hurdles Need Adequate Focus and Resources



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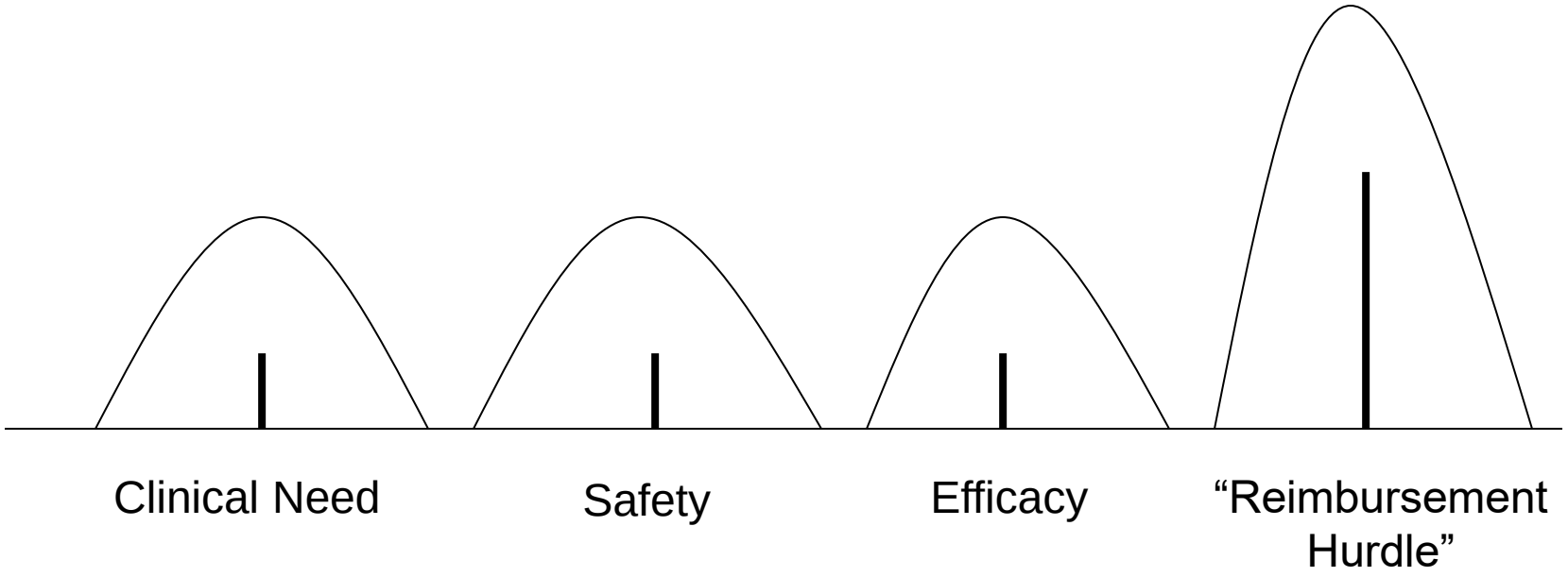
It Takes More and More Effort to Clear the "Reimbursement Hurdle"



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Questions?

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Structure of US Insurance Markets

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Structure of US Insurance Markets

US Population (2023) = ~334,400,000

US Population (2021) = ~327,000,000

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Structure of US Insurance Markets

Payer Market Structure 2021

Employment-Based Insurance:		178,869,000
Directly Purchased/Individual Market:		44,799,000
Medicare (Part B): \	Total Medicare 59.5M	32,138,000
Medicare (Part C): /		27,376,000
Medicaid:		68,997,000
Military Healthcare Coverage (TRICARE):		9,600,000
Uninsured:		28,122,000
Total Coverage Arrangements:		389,901,000

Enrollees in commercial insurance (179 M + 45 M = 224 M) is largest group by far and ~ 3.8 times the size of Medicare.

Of the 299 M insured Americans, there were 362 M insurance arrangements, resulting in 1.2 arrangements per insured person.

Sources: U.S. Congressional Research Service. U.S. Health Care Coverage and Spending (IF10830; Feb. 6, 2023), by Ryan J. Rosso. Text in: Congressional Research Service; Accessed: March 8, 2023.
https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/,
https://www.tricare.mil/About/Facts

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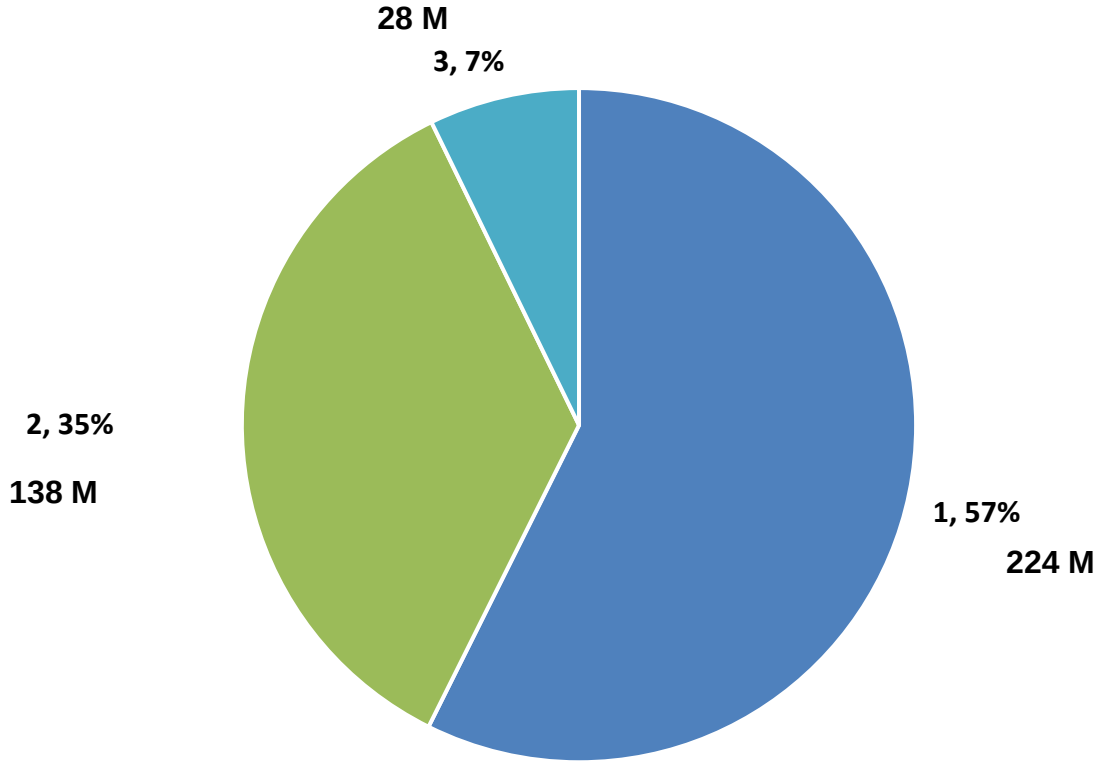
Structure of US Insurance Markets

Over half of all Americans are covered by Private Payors, the most complex and least transparent Reimbursement Process.



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What Is the Biggest Recent Change in Market Structure?

Drop in uninsured:

51 M in 2009

28 M in 2021

Remember the goal of Obamacare was to reduce the number of uninsured.

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Questions?

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Structure of Commercial Insurance

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Who Are The Largest US Commercial Insurers?

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Top 25 Commercial Health Plans

Rank	Health Plan	Covered Lives
1	Elevance Health	31.4 M
2	UHC	26.6 M
3	CVS/Aetna	17.03 M
4	HCSC	15.0 M
5	Express/CIGNA	14.8 M
6	Kaiser Permanente	9.5 M
7	IBX (PA)	8.0 M
8	BCBS MI	6.1 M
9	GuideWell (FL)	6.0 M
10	Highmark (PA)	5.6 M
11	BCBS NC	4.9 M
12	BS CA	4.7 M
13	Horizon BCBS	3.7 M

Rank	Health Plan	Covered Lives
14	BCBS TN	3.4 M
15	Regence	3.4 M
16	CareFirst	3.0 M
17	BCBS MA	3.0 M
18	EmblemHealth	3.0 M
19	BCBS AL	2.8 M
20	Premera BC	2.8 M
21	BCBS MN	2.5 M
22	Wellmark	2.2 M
23	BCBS LA	1.9 M
24	BCBS SC	1.7 M
25	BCBS AR	1.6 M
Total Commercial Membership in Top 25		**184.6 M**

82.4% of total commercial membership in Top 25.

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How Does the World Look to One of These Large Insurers?

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Structure of US Insurance Markets

UnitedHealth Group Total Membership:

A single payer has a foot in several business segments at the same time.

(in thousands, except percentages)	2022
Commercial - domestic:	
Risk-based	8,045
Fee-based	18,640
Total commercial - domestic	26,685
Medicare Advantage	7,105
Medicaid	8,170
Medicare Supplement (Standardized)	4,375
Total community and senior	19,650
Total UnitedHealthcare - domestic medical	46,335
Commercial - global	5,360
Total UnitedHealthcare - medical	51,695
Supplemental Data:	
Medicare Part D stand-alone	3,295

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Structure of US Insurance Markets

UnitedHealth Group Total Membership:

Today, we are talking about commercial health plans. Generally, people mean domestic (U.S.-based commercial business).

(in thousands, except percentages)	2022
Commercial - domestic:	
Risk-based	8,045
Fee-based	18,640
Total commercial - domestic	26,685
Medicare Advantage	7,10[illegible]
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Structure of US Insurance Markets

UnitedHealth Group Total Membership:

Why do health plans break out their business according to "Risk-based" and "Fee-based"?

(in thousands, except percentages)	2022
Commercial - domestic:	
Risk-based	8,045
Fee-based	18,640
Total commercial - domestic	26,685
Medicare Advantage	7,105
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Structure of US Insurance Markets

Insured (Risk-based) versus Administrative Services Only ("ASO" or Fee-based):

- The majority of large accounts and book of business for large insurers are ASO rather than insured.
- Insured: Payments are premiums; premiums cover funds for providers and administrative activities. Checks to providers on insurance company check stock.
- ASO: Employer puts funds in its own account. Funds are drawn from that account and replenished as needed. Additional payments are for "administrative services only." Employer has greater say in what's covered. Thus, the "Self-insured employer" strategy. Use employer check stock.

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Structure of US Insurance Markets

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Questions?

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Considerations for MedTech Companies

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Considerations for MedTech Companies

For most products:

- Medicare Part B is the first mover in deciding coverage and pricing.
- Part C follow soon after Part B.
- Private payers tend to follow Medicare, and their evidence requirements may be greater than Medicare, requiring more publications.
- There are many more commercial health plans than there are MACs. You need to scale team.

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Considerations for MedTech Companies

- Medicare B is done through open process: rule and comment.
- Commercial health plans rely on opaque policy development and confidential contracts.
- Know how the epidemiology of your condition aligns with payers, examples:
  - TAVR – more than 90% of aortic stenosis over 65.
  - Obstructive sleep apnea – occurs in people under 65.
  - Childbirth – Medicaid pays for over half of US childbirths.

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How Do Commercial Health Plans Decide about Coverage?

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Two Step Process:

Is the product/service shown in publications to help people?

Does the product/service have value at the price point being considered?

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The Brake Shop Rule:

Can I go to the brake shop down on the corner that pays my insurance company a premium every month and explain to the owner why she/he is paying an increased premium to cover the new technology?

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Three-By-Three Grid

	New Technology Lower Cost vs. Old Technology	New Technology Equal Cost vs. Old Technology	New Technology Higher Cost vs. Old Technology
New Technology Better Clin. Effectiveness vs. Old Technology	Cover New Technology	Cover New Technology	Incremental Analysis*
New Technology Equal Clin. Effectiveness vs. Old Technology	Cover New Technology	Equipoise	Do Not Cover New Technology
New Technology Lower Clin. Effectiveness vs. Old Technology	Incremental Analysis*	Do Not Cover New Technology	Do Not Cover New Technology

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Expect the greatest amount of pushback to be where the technology is superior.

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In your role, the second hardest thing to do is to convince your company to invest in a study to show the superiority of your product.

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In your role, the hardest thing to do is to convince commercial payers to cover a premium price product without evidence of superiority.

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Three-By-Three Grid

	New Technology Lower Cost vs. Old Technology	New Technology Equal Cost vs. Old Technology	New Technology Higher Cost vs. Old Technology
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A premium price product without evidence of superiority has a challenge.

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Questions?

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Emerging Trends in Commercial Insurance Coverage

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Consolidation:

Elevance Acquires BCBS of Louisiana

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Top 25 Commercial Health Plans

Rank	Health Plan	Covered Lives
1	Elevance Health	31.4 M
2	UHC	26.6 M
3	CVS/Aetna	17.03 M
4	HCSC	15.0 M
5	Express/CIGNA	14.8 M
6	Kaiser Permanente	9.5 M
7	IBX (PA)	8.0 M
8	BCBS MI	6.1 M
9	GuideWell (FL)	6.0 M
10	Highmark (PA)	5.6 M
11	BCBS NC	4.9 M
12	BS CA	4.7 M
13	Horizon BCBS	3.7 M

Rank	Health Plan	Covered Lives
14	BCBS TN	3.4 M
15	Regence	3.4 M
16	CareFirst	3.0 M
17	BCBS MA	3.0 M
18	EmblemHealth	3.0 M
19	BCBS AL	2.8 M
20	Premera BC	2.8 M
21	BCBS MN	2.5 M
22	Wellmark	2.2 M
23	BCBS LA	1.9 M
24	BCBS SC	1.7 M
25	BCBS AR	1.6 M
Total Commercial Membership in Top 25		**184.6 M**

82.4% of total commercial membership in Top 25.

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Top 25 Commercial Health Plans

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20	Premera BC	2.8 M
21	BCBS MN	2.5 M
22	Wellmark	2.2 M
23	BCBS SC	1.7 M
24	BCBS AR	1.6 M
25	*Excellus BCBS*	*1.6 M*
Total Commercial Membership in Top 25		**186.1 M**

83% of total commercial membership in Top 25.

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Consolidation Makes It More Important to Know Well The Folks Running The Largest Commercial Health Plans

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Pay-vidors:

Aggressive Vertical Integration Is Again the Norm.

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Old School Pay-vidors

- Kaiser-Permanente now has ~10M health plan members. Kaiser-Permanente was created in the 1920s to serve employees of the company building the Colorado River Aqueduct.
- The Health Plan Alliance is an affiliate of the VHA. It consists of 48 health system-owned health plans with approximately between 10 and 15 M total health plan members.

Source: https://www.healthplanalliance.org/assnfe/CompanyDirectory.asp?MODE=FINDRESULTS

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New School Pay-vidors

- The largest pharmacy chain in the US (CVS) purchased the third largest health insurance company in the US (Aetna). Oak Street offer out.
- UnitedHealthGroup is the single largest employer of **physicians** in the US.
- Vertical integration wants to exploit certain synergies. So, the underlying business rules are likely to change.

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Questions?

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Conclusions

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Conclusions

- How a society finances its health care reflects its values and is in constant evolution.
- Commercial health plans serve 224 M Americans, 3.8 times the number that Medicare serves.
- Commercial health plans, as a general rule, move after Medicare Parts B & C to cover services.
- Commercial health plan coverage process tends to be opaque.
- Commercial health plans typically require more evidence than Medicare.
- Commercial health plans, as a rule, are price sensitive.
- While the pay-vidor model is old and established. Right now, it is growing rapidly; commercial health plans are active here.

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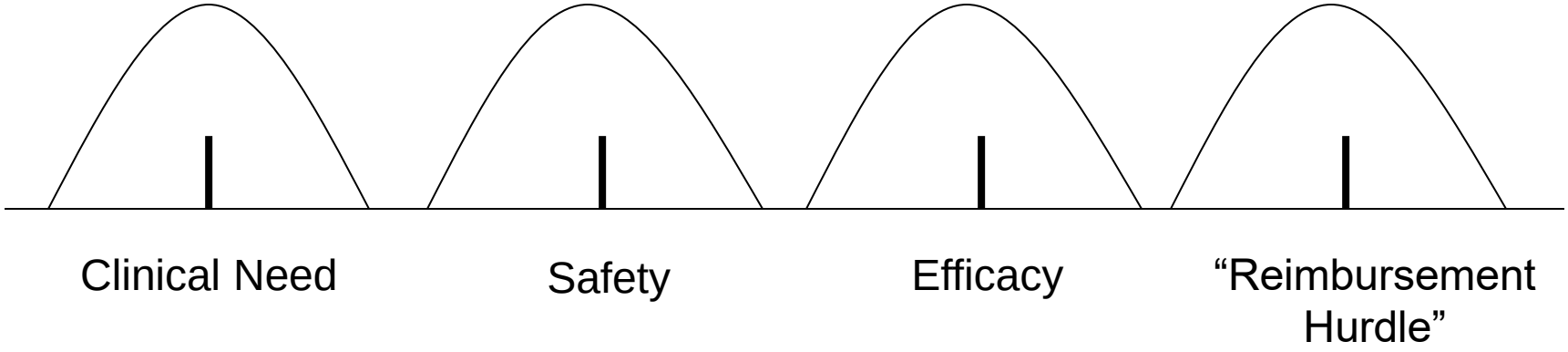
All Four Hurdles Need Adequate Focus and Resources



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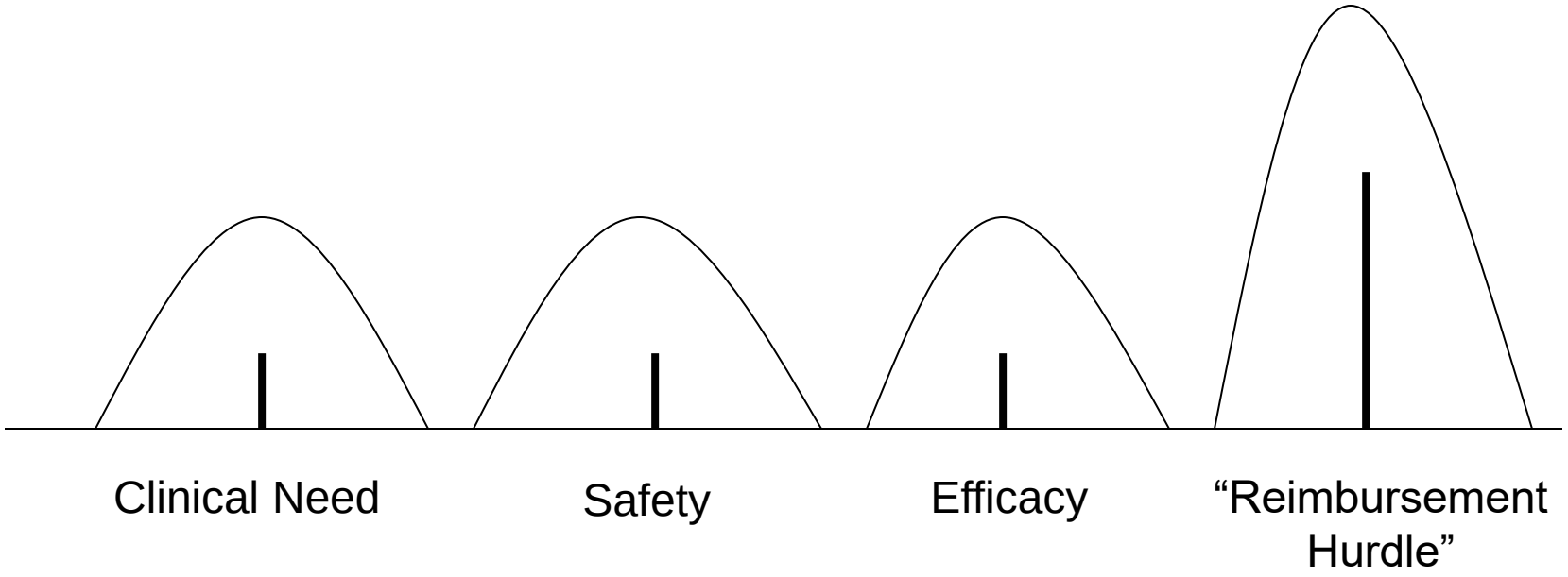
It Takes More and More Effort to Clear the "Reimbursement Hurdle"



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Thank You!!

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Deloitte.

AdvaMed
Advanced Medical Technology Association

MedTech Value Framework

April 26, 2023

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Agenda

1. **Objectives and Principles for MedTech Value Framework**
2. **Key Digital and Environmental, Social and Governance (ESG) Trends**
3. **MedTech Value Framework**

Objectives and Principles for MedTech Value Framework

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Objective and Overview of the MedTech Value Framework and Refresh

DIGITAL HEALTH SOLUTIONS

The **MedTech landscape** has witnessed significant changes and advancements, especially with the addition of **new digital solutions** and a **paradigm shift** in industry towards **Environmental, Social, and Governance** strategic mindset.

ESG STRATEGY & TRENDS

These recent market changes/shifts warrant the need for a refresh to the Value Framework which considers the **value perception and drivers** associated with medical technologies by payers, providers, PBMs, patients, and other **stakeholders**.

VALUE ASSESSMENT BY STAKEHOLDERS

Key Digital & Environmental, Social and Governance (ESG) Trends

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Key Trends | Digital Health Solutions (1/2)

Digital health solutions are increasingly expanding the horizon of MedTech use cases and helping improve stakeholder outcomes with changing preferences and innovations

TREND	***Changing patients & HCPs preferences**, confidence, and expectations in digital health technologies post-Covid*	***Technological innovations,** smartphone proliferation, evolution of technologies (IoT, AI), and investments in emerging technologies (AR/VR, robotics)*	***Data-driven insights and real-world evidence** to ensure patient-centric and value-based care*
USE CASES	**Patient Engagement Tools:** • Virtual Visits and Service Operations • Data Management • Patient Care Management • Strategy & Analytics **Physician Assistance Tools:** • **Physician/Clinical Support Tools**: Workforce Mgmt. Portal, OT/ICU Automation Tools, Device Data Management & Analytics • **Operations Management Tools**: Billing and Claims Processing, Inventory Management • **Physician Engagement Tools**: Virtual Events, Remote Meeting with reps, Digital KOL	**AI/ML**: Screening, Diagnostics, Treatment, Operations Management **Robotics:** Surgical Robots, Exoskeletons, Care Robots etc. **AR/VR:** Medical Training, Surgical Assistance and Patient Experience **IoT/IoMT**: IoT for Hospitals, IoT for Payers, IoT for Patients **3D Printing**: Custom-Designed Prosthetics, On-site Printing, Replica Practice Organs	**Real-Time Patient Monitoring with sensors:** Measure and transmit physiological data in real-time **Connected Devices:** Platform to share and view interoperable data across devices **Digital Therapeutics:** Covering the entire spectrum from companion devices to evidence-based personalized therapeutic interventions to patients delivered via software
EXAMPLE	**Image Guided Therapy** *Optimizes workflow using AI-based visualizations and patient management, billing automation & robotics innovations*	**Virtual Reality** *Displays holograms on a real-life patient (e.g., cardiovascular system) or anchor a simulated object during training or surgery*	**Smart Platform** *Smart Platform connects medical devices & clinical systems to empower clinicians to make better insight-based decisions*

Key Trends | Digital Health Solutions (2/2)

Increased cost of care, prevalence of chronic conditions, and regulatory and behavioral changes brought on by the pandemic have advanced the shift to virtual care and new government initiatives and policies

TREND	***Shifting care to low acuity sites and*** *increasing number of early patient discharges for recovery at home drives demand for* ***virtual care***	***Government initiatives*** *to decrease healthcare costs, improve health outcomes, provider greater convenience to patients and increase patient safety & privacy*
USE CASES	**Care Across Low Acuity Sites and Virtual Channel** • Hospital at Home • Virtual Home Care • At-home Diagnostics (driven by Covid) • Condition Management • Acute Care • Emergency Care • Ambulatory Care & Triage • Retail Clinics Additionally, MedTech is segmenting facility on basis of innovativeness to build in their value proposition **Virtual Clinical Trial** All or part of clinical trials are conducted virtually & are enabled by digital technology and supply chain	**Virtual Care** • Permanent Telehealth Changes • Hospital Without Walls Program • CMS coverage expansion of continuous glucose monitors (CGMs) to a broader group of patients **Price Transparency Rules** • Transparency in Coverage Final rule **Interoperability** • Interoperability & Patient Access Rule **Alternative Payment Models (APM)** • MACRA: Medicare Access and CHIP (Children's Health Insurance Program) Reauthorization Act • Changes to Anti-kickback Status & Stark Law
EXAMPLE	**Remote Heart Monitoring** *Handheld reader to send heart device data to physicians; detects anomalies, improves quality of life & reduces ER visits*	***NA***

Key Trends | ESG for MedTech

The imperative for healthcare organizations to adopt and invest in ESG principles and values has become more apparent as consumers, communities, employees, investors and government have been increasingly putting pressure for ESG adoption

Market Drivers

Increased **investors'** expectations for organizations to ensure **corporate responsibility** and more scrutiny of companies' ESG profiles

Employees are more likely to view in a positive light and support organizations that is proactive towards ESG initiatives

Diversity, Equity and Inclusion (DEI) initiatives like gender, racial, income etc. based diversity in employees and activities such as clinical trials

Customers outlook towards companies turns **positive** if it's taking action to **address inequity in Social Determinants of Health (SDoH)***

Access to care has emerged as a major driver especially after pandemic with a **focus to reach the underserved** with agility and cost-effectiveness

Technology innovations have led to cost and **environmental effectiveness**, e.g., AI for improving device efficiency, rapid prototyping using 3D printing, blockchain-enabled tracking of supply chain, etc.

Regulators focus on **disclosures** related to emissions & climate change; SEC also proposed new disclosure requirements following Biden administration's pledge for **net-zero emission economy goal** for 2050

Note: *SDoH: Non-medical factors like economic policies and systems, development agendas, political systems, social norms, etc. which influence health outcomes.

Key Trends | Additional Stakeholders

Employees and Investors/Donors are impacted by ESG initiatives (especially Environment and Social) in MedTech in the following ways

IMPACT OF ESG INITIATIVES ON STAKEHOLDERS

Employees

Provides an attractive value proposition for talent retention

Organization's ESG value proposition is a **key to attracting & retaining talent**, especially Gen Z and Millennials

Increases employee's productivity

Being part of an organization with a robust ESG strategy and meaningful efforts **increases employee's motivation** by instilling a sense of purpose, and thereby improving overall productivity

Improves employee's health & well-being

ESG **efforts** helps improve employee's health and wellness, thereby increasing talent retention and productivity

Investors (For-Profit) or Donors (Non-Profit)

Incorporates ESG evaluation in credit rating

S&P, Moody's and Fitch Ratings have incorporated **ESG evaluations in their credit ratings** of companies

- Social factors are top considerations in the company's ESG reviews due to rising costs of care, access & safety risks, followed by environmental factors

Impacts company's perception and differentiation

Companies having ESG initiatives such as improving health equity, reducing Greenhouse Gas (GHG) emissions etc., **earns more trust** and differentiation from investors and donors

- Investors and donors are **increasingly asking questions** about a company's ESG practices
- ESG reports, press releases, and **data-driven reporting metrics** such as "healthy days", affordable homes and maternal health metrics etc. helps investors to understand a company's ESG value proposition

MedTech Value Framework

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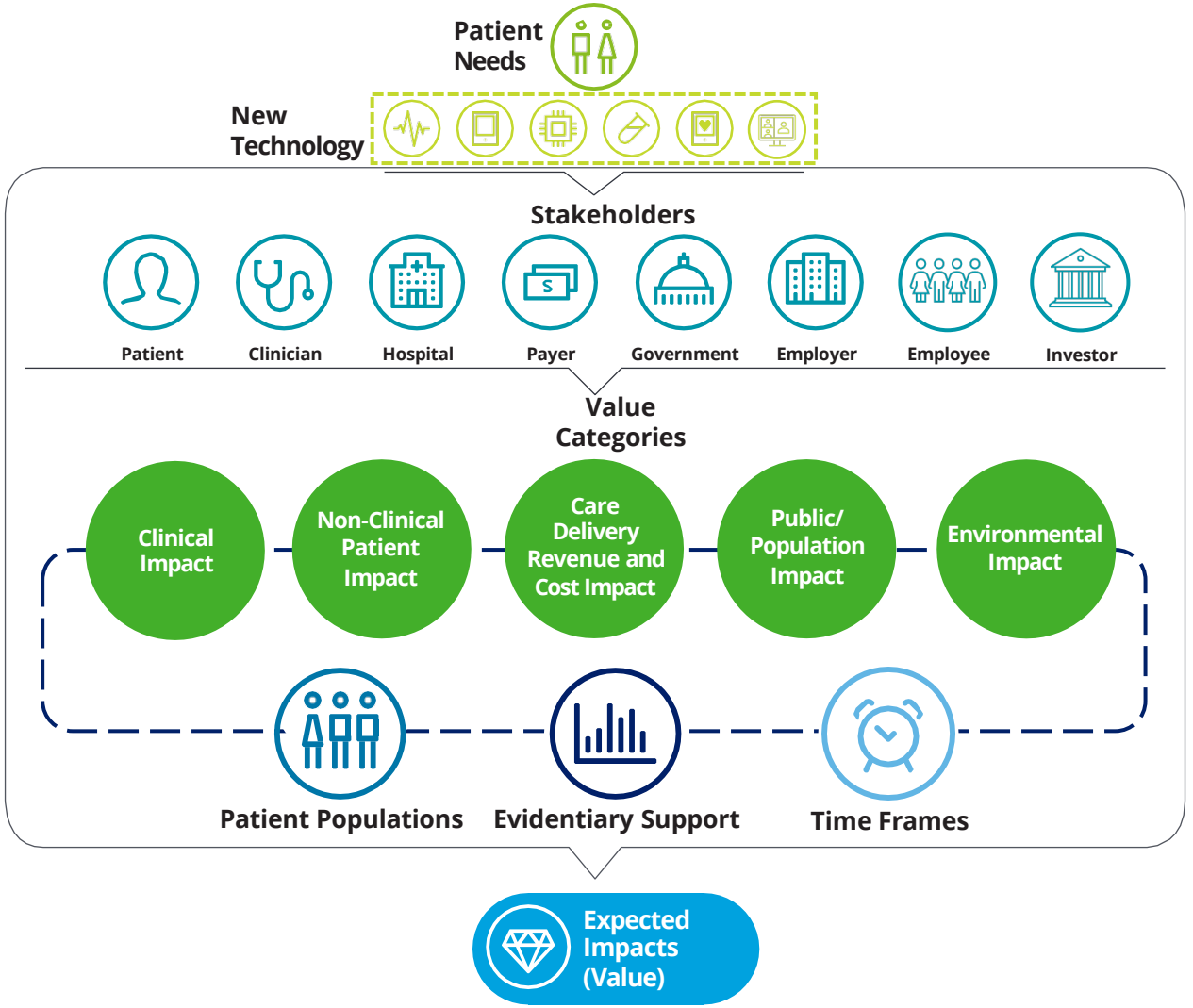
Principles for Effective Value Management

The Comprehensiveness Principle	Value assessments should consider a broad array of patient-centric value drivers and their relevance and importance for **different stakeholders**
The Evidentiary Principle	Value assessments should utilize an appropriate **range of available evidence** and the **type of evidence** and assessment methodology should be based on technology type and the potential risk to patients
The Cost Principle	Value assessments should consider and report **costs incurred/avoided** over timeframes appropriate for the technology (including, where available, costs incurred and avoided outside the health care system)
The Specificity Principle	Value assessments should account for representative patient populations and applicable **timeframes for patient impact**
The Flexibility Principle	Value assessments should be flexible to account for **different types of medical technologies** and utilize an appropriate range of impact analyses
The Engagement Principle	Value assessment processes should involve the perspectives of **multiple stakeholders** and provide sufficient opportunities and time for all to engage in the process
The Transparency Principle	Value assessment processes and methodologies should be **transparent to all stakeholders**
The Relevancy Principle	Value assessments should be **updated regularly** to keep pace with innovation in standards of care or when there is significant new evidence

MedTech Value Framework

Value Framework: Comprehensive approach for assessing MedTech value



Use Case Development

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An Important Callout about Use Cases

Rationale behind Use Case Choice

- The use cases were selected to ensure that the **newly added modifications**, in addition to the existing value drivers in the Value Framework, could be **tested for broad applicability and resiliency**
- No other considerations were attached during the selection of use cases
- The use cases selected by no means represents an exhaustive set of use cases and other use cases (selected by AdvaMed) could be considered instead

What a use case IS

- A way of demonstrating the various **steps involved** in the application of the process
- A **test case** of the value framework aimed at demonstrating the feasibility of the underlying complexity, excluding the development of a pricing model or sensitivity analysis

What a use case IS NOT

- **Not a complete/comprehensive application or final output** of the value framework
- **Not a price comparison** between different technologies
- **Not a sales/marketing handout**– instead, they are intended as internal documents to generate stakeholder consensus on the potential application of the framework

Use Case Guidelines

The key use case development considerations mirrors the value assessment process

Value Assessment Process	Use Case Guidelines
Goals and Purpose of Value Assessment	• What is the **unmet need** and how does the technology **address it**? • What **alternative technologies** or treatments will the technology be compared against? • Why is the value assessment being created (i.e., for what **purpose**)?
Stakeholder(s) Involved	• **Who** are the key stakeholders?
Value Drivers	• What are the ways this medical technology creates **value versus alternatives** (value framework 'value drivers')?
Patient Populations	• How does the **value vary** for different patient populations?
Time Frames	• How should **different time frames** be considered in the value assessment?
Evidentiary Support	• What **types of evidence** are available to support the value assessment?
Output	
Expected Impacts (Value)	• What are the expected impacts? • What **types of analyses/scenarios** would you expect to use to ensure stakeholders understand the value of your technology?

Use Case: Post-Surgery Care Management Platform (1/2)

Product Overview: Digital care management platform that uses smartphone and wearables to help deliver support and guidance to the patients by continuous data and patient-reported feedback

Stakeholders Impacted

Patient Needs *Improving joint movements and getting back to normal routine faster after surgeries such as total knee replacement*

New Technology *Condition Monitoring to raise alert when a patient's walking speed is slower than expected, relative to their surgery date; Ability to modify patients' care plan and intervene; Self-directed exercises to reduce supervised physical therapy*

Stakeholders

Patient | Physician | Hospital | Payer | Government | Employer | Employee | Investor

Value Categories

Clinical Impact | Non-Clinical Patient Impact | Care Delivery Revenue and Cost Impact | Public/ Population Impact | Environmental Impact

Patient Populations

Patients of all genders having knee joint replacement, age of above 18

Evidentiary Support

White papers by the manufacturer on care management platform's ability to impact experience, technology adoption, outcomes, and cost of care

Time Frames

Total duration of monitoring is usually 12 months with surveys at around pre-operative phase and at 1 month, 3 month, 6 months, and 12 months after surgery

Expected Impacts (Value)

Clinical

Improves clinical outcomes, clinical decision making, and patient compliance

Non-Clinical

Improves patient access, patient experience and decreases OOP expenses

Care-Delivery Revenue & Cost

Enhances provider experience

Public/Population

Reduces burden on healthcare systems, rehabilitation costs, and time to return to work

Environmental

Reduces waste generated, carbon footprint and energy use as compared to alternative therapies requiring physical visits

Note: Analysis done based on secondary research & Deloitte analysis

ILLUSTRATIVE

Use Case: Post-Surgery Care Management Platform (2/2)

Value Categories

Clinical Impact

- Positively influences **patient outcomes** and range of motion
- Improves patient outcomes and decreases cost of care by **decreasing readmission rates** & **ED visits**
- Improves **patient compliance** & engagement
- **Reduces burden of on-site patient follow-up care** for both short and long term
- Manages well-being of most at-risk patients effectively, eliminating unexpected outcomes
- **Enhances clinical decision making** and ability to produce and report patient reported outcomes for quality metrics

Non-Clinical Patient Impact

- **Improves patient experience** and decreases patient **anxiety** as compared to other medical and surgical experiences
- Improves patient satisfaction via enhanced patient engagement, **personalized insights and education** throughout surgical journey
- Reduces potential **cost of unnecessary patient visits** using guidance from video, picture or text
- Decreases **out-of-pocket** physical therapy **expenses**

Care Delivery Revenue and Cost Impact

- Enhances healthcare professional experience by providing **integrated data** (mobility, heart rate, engagement, gait quality, etc.) and **interoperability** with other devices

Public/ Population Impact

- Reduces burden on healthcare system as **unnecessary patient visits are avoided**
- **Decreases time to return** to work
- **Enhances access to care** with providers' visibility, where providers can review the patient's progress in real-time
- **Improves care coordination** among the stakeholders
- Decreases overall **healthcare costs**
- Lowers **rehabilitation costs**

Environmental Impact*

- **Decreases energy use and carbon footprint** as compared to alternate therapies requiring physical visits
- **Reduces** the need for **manufacturing and using** monitoring device since smartphones/wearables allow early interventions

Key Stakeholders

Patient | Physician | Hospital | Payer | Government | Employer | Employee | Investor

Note: **We believe these environmental impact could be added in the product's value proposition, even though the manufacturer doesn't currently include this in the expected value delivered*

Appendix –MedTech Value Framework (Detailed)

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MedTech Value Framework | Clinical Impact

No changes to Previous Framework *Changes to Framework owing to Digital Health trends* *Changes to Framework owing to ESG trends in MedTech*

Value Categories	Value Subcategories	Value Drivers	Sample Questions to Consider	Sample Value Metrics
Clinical Impact	**Clinical Efficacy and Effectiveness**	Improvement in clinical outcomes (disease- specific morbidity measures, reduction in mortality, reduction in rate of disease progression, and reduction in the burden of follow-up care)	• How does the technology affect clinical outcomes compared to other treatment options (whether vs. direct competitive offerings or vs. alternative treatments or care plans)? • How does the technology impact the rate of disease progression? • How does the technology impact the burden of follow-up care (short- and long-term), function, activities of daily living (ADLs)? • How does the technology change patient recovery time and/or post-surgical care (e.g., number of follow-ups, intensity, site of care, rehabilitation)? • How does the technology ensure care gaps are closed (e.g., via data-driven personalized care, preciseness of care delivery)? • How does the technology improve clinical decision-making (e.g., with access to patient data, interoperability)? • How does the technology provide real-world economic and clinical value in various settings (e.g., acute sites)? • How does the technology ensure that needs of different sub-populations, including under-represented population, are accounted for?	• Survival rate (e.g., overall survival, progression-free survival) • Morbidity endpoints based on disease progression (e.g., disability/mobility ratings like Framingham score, Kaplan Meier score) • Length of time to reach key recovery milestones (e.g., ADL milestones) • Degree of invasiveness • Number/severity of post-care complications • Readmission rates; Hospital Compare scores • Hospital-acquired infection rates • Number of follow-ups • Number of repeat procedures (e.g., revision surgeries) • Utilization of various categories of services (e.g., post-acute care) • Incremental Clinical Effectiveness Ratio (ICER)[1] • Time to serve patient (e.g., 4 min response for stroke)[2] • Number of visits to correct diagnosis[3] • Number of ED visits[4] • Reduction in patient transfers[2]
		Improvement in compliance with plan of care	• How does the technology influence patient compliance or engagement in their plan of care?	
	Patient Safety and Tolerability	Improved patient safety and tolerability vs. alternative treatments Effect on patient risk tradeoffs basis safety profile and outcomes	• How does the technology impact patient safety (lower/higher risk of complications, less/more invasive, etc.) relative to available alternatives? What is the effect on patient risk tradeoffs?	• Incidence or rate of adverse events • Severity of adverse events and side effects • Usability
		Impact on security and privacy (technology and data)	• How does data security and privacy compare to other available alternatives?	• Frequency of data breaches • Compliance to data security and privacy standards (e.g., HIPAA Rule*)[5]
	Quality of Life	Improvement in quality of life (physical and social well-being)	• How does the technology address regaining function, including mobility, re-integration into daily life, improvement in activities of daily life, etc.? • How does the technology impact quality of life (physical and social well-being) in the short and/or long term?	• Quality-adjusted life years (QALY)[#] • Disability-adjusted life years (DALY)[#] • Health-adjusted life expectancy[#] • Quality-adjusted life expectancy[#] • Patient perceived/reported outcomes (PROs) – across physical, mental (emotional), and social health measures (e.g., SF12, SF36, EQ5D) • Caregiver-perceived outcomes (caregiver ratings of patient QOL using utility indexes such as the European Quality of Life-5 Dimensions Scale – a global QOL visual analogue scale) [#] *Commonly accepted clinical impact metrics*

Source: 1. ICER Value Framework; 2. Intouch Telehealth Stroke Solution; 3. Philips Image Guided Therapy; 4. Medtronic Remote Heart Monitoring; 5. HIPAA Rule
Note: *Health Insurance Portability and Accountability Act (HIPAA) of 1996 has a goal to assure that individuals' health information is properly protected while allowing the flow of health information

MedTech Value Framework | Non-clinical Patient Impact

No changes to Previous Framework *Changes to Framework owing to Digital Health trends* *Changes to Framework owing to ESG trends in MedTech*

Value Categories	Value Subcategories	Value Drivers	Sample Questions to Consider	Sample Value Metrics
Non-clinical Patient Impact	**Patient Experience**	Preferable site or channel of care (ease of access)	• Does this technology create more/ less preferable options for the patient (e.g., more accessible care settings, less intensive care settings)? • Does this technology increase convenience (both short and long term) to patients and allow faster and easier access to care (e.g., reduced waiting or commute time)?	• Patient preferences (e.g., preference for care settings) • Median travel time for patient[1] • Wait time for patient[1] • Time invested in follow-up care by patient[2]
		Effect on patient's active engagement in self-care journey	• How does the technology improve patient's access to easy-to-comprehend data and actionable insights to enable them to stay informed of their health? • How does the technology help improve patient adherence to the treatment (e.g., via patient assistance mHealth apps)?	• Medical adherence (self-reported, proportion of days covered, etc.)[3] • Daily Active Users[4] • Customer Experience Score[4] • Task Completion Rate (for patient)[5] • Net Promoter Score[5]
		Predictability of care/ experiences vs. expectations	• How does the technology impact the patient experience? • How does the technology contribute to the patient, family, and caregiver experience of care related to quality, safety, and access across settings? • How does the technology enable patients and their families and caregivers to navigate, coordinate, and manage their care appropriately and effectively? • How does the technology address predictability of care?	• Number, intrusiveness of follow-ups • Number of repeated procedures • Patient experience evaluation metrics (e.g., Hospital Compare ratings, CAHPS)
		Reintegration/ reengagement of patient into society	• How does the technology affect ADLs, mobility, returning to work, etc.?	• SF 36 • Caregiver quality of life (physical, social, financial, etc., as contained in the Zarit Burden interview and other indices) • Time invested by caregivers[6]
		Reduced burden on caregivers due to better patient experience and outcomes	• How does the technology reduce the burden on caregivers and improve ease of use/adoption of technology?	
	Patient Economics	Impact on out-of-pocket (OOP) patient expenses	• How does the technology impact affordability of treatment/OOP expense for different patients? • Does the technology enable early intervention and provide more efficient or precise care, reducing overall cost? • Does the technology have price transparency allowing patients to make an informed provider choice?	• OOP cost to patient/family over the course of disease progression and treatment
		Reduced time to return to ADLs	• Does the technology help the patient return to ADLs and, therefore, the workforce faster? • Does the technology require less one-to-one care and patient monitoring, which will decrease caregiver/nursing expenses?	• Patient recovery milestones (e.g., ADLs, walking, time to return to work)

Source: 1. Xtelligent Healthcare Media; 2. Zimmer myMobility; 3. NCBI- Estimating PDC; 4. Tracx Customer Experience Metrics; 5. Philips Patient Management Solution; 6. NCBI- Caregivers

MedTech Value Framework | Care Delivery Revenue & Cost Impact

No changes to Previous Framework | *Changes to Framework owing to Digital Health trends* | *Changes to Framework owing to ESG trends in MedTech*

Value Categories	Value Subcategories	Value Drivers	Sample Questions to Consider	Sample Value Metrics
Care Delivery Revenue and Cost Impact	**Quality of Care Economics**	Economic impact of performance-based reimbursement metrics (e.g., hospital-acquired infections, readmissions, LOS, cost efficiency)	• How does the technology enable the right choice of treatment, for the right patient, at the right time, at the right place? • How does the technology impact the economics associated with the quality of care provided? • What are the direct and indirect cost benefits of improved quality of care?	Costs related to: • Incidence/severity of post-care complications • Rate of readmissions, especially unplanned/ preventable; Hospital Compare scores • Incidence/rate of hospital-acquired infections and pressure ulcers • Number of follow-ups • Number of repeat procedures (revision surgeries) • Reduced harm from inappropriate or unnecessary care • LOS • Use of post-acute care and other categories of services • Patient satisfaction scores (e.g., based on expectations met, comfort) • Errors in triage[1]
	Care Efficiency and Experience	Economic impact of improved system throughput and workflow/ efficient time and resource utilization (clinician's time and effort, automation, disposable utilization, site of care, staff utilization, OR utilization, service / maintenance, LOS, time in ICU/ED)	• How does the technology affect costs-related to system throughput, workflows, device/technology setup and maintenance, and care efficiency (site of care, staff)? • What are the meaningful reductions in time and resource utilization for the system in the short term and long term? • How does the technology affect costs-based on the reduction of patient no-shows, elimination of waste and unnecessary procedures? • How does the technology affect the administrative effort and staff utilization in managing data (e.g., duplication, documentation)? • How does the technology impact care productivity and capacity to grow revenue by new patient acquisition and improved retention?	Costs related to: • Number and types of services used • Utilization of less-expensive services • Patient flow (i.e., overall impact on system efficiency) • Procedure times • Consumption of materials • Human resource and staff/OR utilization • Length of recovery time • Patient no-shows[2] • Average late visits by patient[2] • Set-up and operational cost of technology[3] • Time and resources in administrative tasks (e.g., documentation, coordination)[3] • Technological issues, such as service outages, etc.
		Impact of costs associated with clinical outcomes variance	• How does the technology help reduce costs associated with variance in clinical outcomes across individual clinicians/sites of care?	• Costs associated with clinical outcomes variance
		Economic impact of improved adoption of new care practices (due to easier/more effective training/education or easier access/usage of data and technology)	• How does the technology affect costs based on the improvement in adoption of new care practices due to improved ease of use? • How does the technology impact the economics associated with clinician engagement and satisfaction (e.g., easier data access, improved workflow visibility and management, etc.)?	• Training and education time (hours) and costs • Clinician turnover[4] • Clinician engagement with work[5] • Perceived effectiveness of technology[6] • Perceived ease of use of technology[6]

Source: 1. Intouch Telehealth Stroke Solution; 2. Philips Patient Management Solution; 3. Tripleaim Software; 4. AMA Return on Health Report; 5. Forbes Technology Council; 6. ResearchGate Perceived use of IT

MedTech Value Framework | Public and Population Impact

No changes to Previous Framework | *Changes to Framework owing to Digital Health trends* | *Changes to Framework owing to ESG trends in MedTech*

Value Categories	Value Subcategories	Value Drivers	Sample Questions to Consider	Sample Value Metrics
Public and Population Impact	**Population Health**	Improved population health (burden of illness/ disease)	• How does the technology impact overall public and population health measures (e.g., life expectancy free of disability)?	• Quality-adjusted life years (QALY) (population) • Disability-adjusted life years (DALY) (population) • Health-adjusted life expectancy (population) • Quality-adjusted life expectancy (population) • Overall survival • Child mortality
			• How does the technology address any socioeconomic disparities in care? • Does the technology address patient clinical outcomes, improve quality and safety due to health disparities? • Does the technology help improve patient, family, caregiver, and clinician experience due to health disparities?	• Rate of utilization across socioeconomic categories • Cost of serving underserved population
			• How does the technology impact patient access to care (e.g., access across geographies, at home, due to socioeconomic barriers etc.), including equitable access to health technology and data?	• Patient access (# of patients) • Percentage of patients who delay care due to access barriers[1] • Cost of Serving underserved population
			• How does the technology help people re-engage in society?	• Time to return to work • Function/ADLs
		Impact to overall private and public health care cost	• How does this technology impact overall health care costs, private and public? • Does the technology impact overall health care costs and efficiency by addressing health inequities as one of the key drivers?	• Overall health care cost ($) per capita
		More efficient private and public spending	• How does the technology help lower unnecessary private and public spending? • How does the technology help in targeted spending to meet population health goals via access to quality data/trends (ease of data interpretation, actionable insights, etc.)? • How does the technology help manufacturers improve device based on data-driven insights?	• Amount of public spending ($) • Reproducibility (same outcome when two different medical staff use the technology) • Accuracy (same outcome if the technology is used more than once)
	Workforce Productivity	Increased employee productivity (reduced absenteeism, improved presenteeism)	• How does this technology impact employee productivity and attendance? • How does the technology impact employee's general health and wellness and provide a sense of purpose? • Does the technology have an impact on the organization's ESG value proposition, which in turn positively affects employee's sense of purpose/belonging and attraction/retention towards the company?	• Employee absences (#) • Presenteeism • Time to return to work
		Increased caregiver productivity (reduced absenteeism, improved presenteeism)	• How does the technology impact ability for caregiver to provide care, and address productivity and attendance?	• Caregiver absences (#) • Presenteeism

Source: 1. AMA Return on Health Report

MedTech Value Framework | Environmental Impact

No changes to Previous Framework *Changes to Framework owing to Digital Health trends* *Changes to Framework owing to ESG trends in MedTech*

Value Categories	Value Subcategories	Value Drivers	Sample Questions to Consider	Sample Value Metrics
Environmental Impact	**Monetary Impact**	Impact on cost due to environmental initiatives and execution	• How does the technology impact cost reduction due to environment-friendly initiatives in manufacturing, packaging, use, and disposal of devices?	• Single-use plastic usage[1] • Waste generated in packaging or sterilizing[1] • Waste generated in upstream and downstream process due to device use[2] • Energy reduced by using device over alternatives[3] • Total energy and percentage of renewable energy used in manufacturing[4]
		Increased asset optimization by capital allocation in sustainable devices	• How does the technology enhance investment returns over a given period (e.g., extended life of a medical device)?	• Device longevity[4] • Recyclability of device[1] • Availability of closed-loop recycling[4]
	Perception and Differentiation	Impact of reduced net global emissions on company value proposition	• How does the technology support sustainable practices which lead to reduced net global emissions, improving stakeholder perception, and value differentiation?	• Green House Gas emissions[1] • Water usage[1] • Safety of materials and packaging[1]
		Reduction in regulatory, legal, and activist shareholder interventions	• How does the technology help in compliance with environmental best practices, reporting environmental metrics, and price transparency?	• Financial penalties • Claims for compensation • Legal costs

Source: 1. Med Device Online; 2. ResearchGate Environmental Impact of Insulin Infusion Sets; 3.Philips Image Guided Therapy Environmental Impact; 4. Johner Institute Medical Device Sustainability;

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STRATEGIC MARKET ACCESS

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April 25, 2023

WHAT IS MARKET ACCESS?

The strategic science of creating patient and physician access to therapies by:

- identifying,
- measuring,
- comparing and
- communicating the clinical, economic and humanistic value of interventions under consideration

ENABLING COMMERCIAL PULL-THROUGH

CREATING MARKET ACCESS PLAN

Anticipate and shape health policy

Build evidence platform to support the value proposition

Support commercial team with value communication education and tools

Understand Regulatory Framework for Reimbursement

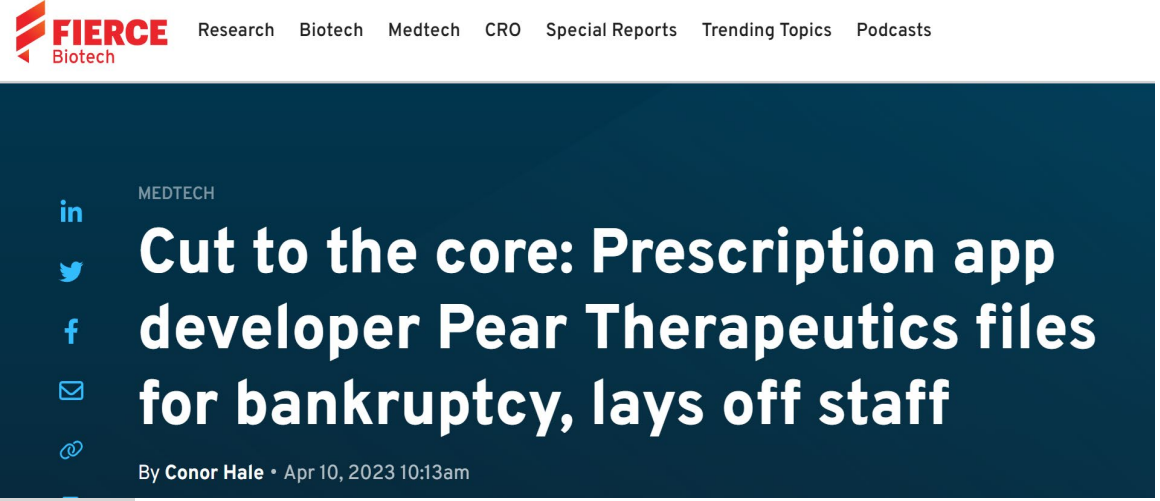
Key Regulation

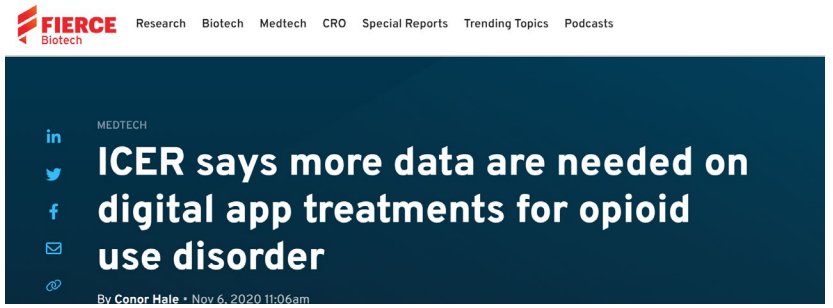
- Medicare Law 1965
  - Benefit Category
- CMS Annual Rulemaking
- 21st Century Cures Act

Upcoming Telehealth Policy Changes

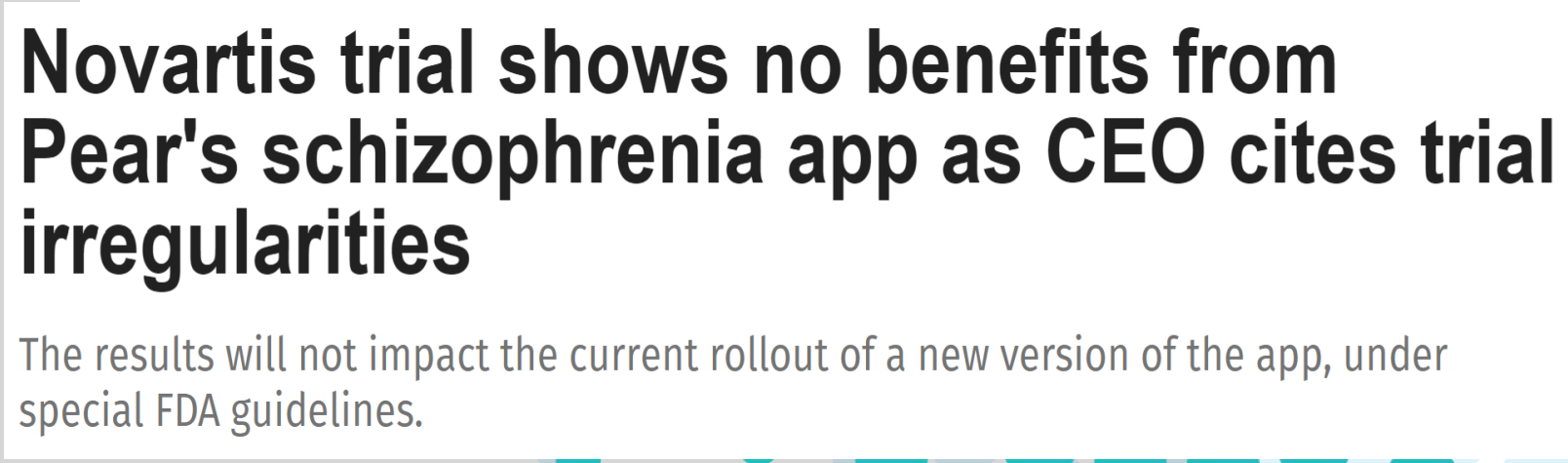
The Administration's plan is to end the COVID-19 public health emergency (PHE) on May 11, 2023. **The CMS recently published policy updates for Medicare telehealth services.**

- **Medicare Clinician Services:**
  - CMS clarified that temporary telehealth services added during the COVID-19 Public Health Emergency (PHE) will continue through the end of Calendar Year 2023.
  - Telehealth services provided in the office setting will continue to be paid at the non-facility rate (higher payment) through the end of Calendar Year 2023.
  - CMS will not implement new codes for remote therapeutic monitoring (RTM) as initially proposed.
- **Medicare Hospital Outpatient Services**: CMS finalized a permanent policy allowing clinical staff of hospital outpatient departments including Critical Access Hospitals to provide remote behavioral health services to patients in their homes.
- **Home Health Agencies**: CMS is adding new billing codes for Home Health telecommunications technology (PDF). Agencies may voluntarily report the codes starting January 1, 2023 but must report these codes starting July 1, 2023.





SAMD Case Study



Key Inflection Points:

Regulatory Strategy

No CMS/Payer Strategy

Unfocused Value Strategy

Weak Evidence Plan

ICER Evaluation: 3-month data

Novartis Trial

Define and Support Value Proposition

Define Product Position

Define Product Value to Stakeholders

Perform Market Assessessment

Support commercial team with value communication education and tools

Matrix Value Team

R & D and Product Management

- Product development
- Product life cycle management
- Features /benefits
- Value Communication

Health Economics & Clinical/Medical Affairs

- Comparative analysis of costs and consequences
- Reimbursement risks & opportunities & MA planning
- Government policies
- Value Propositions
- Value quantification & demonstration
- Value identification, demonstration, determination
- Effectiveness
- Value Communication

Brand Communication, Marketing & Business Development

- Market conditions
- Competitor landscape
- Benefits & differentiators
- Marketing strategy
- Value determination
- Value propositions
- Value communication

Sales, Finance

- Sales strategy
- Value realization (pricing)
- ASP and GPM% (bandwidth)
- ROI

QA/RA

- Safety & regulatory issues
- Pre-market studies
- Efficacy
- Value Propositions
- Value communication

Define Product Position

Supply

- 510K – No Clinical data
- Substantially same as Predicate
- No differentiated Reimbursement

Quick to Market

Therapy

- Clinical Data needed for Reimbursement and Regulatory Approval (DeNovo or PMA)
- Comparative Published Outcomes data required for Coverage
- New Coding Map likely needed

Time and Resources Intensive

Define Product Position

Technology

- [ ] Devices
- [ ] Diagnostics
- [ ] SAMD*

Value Measure

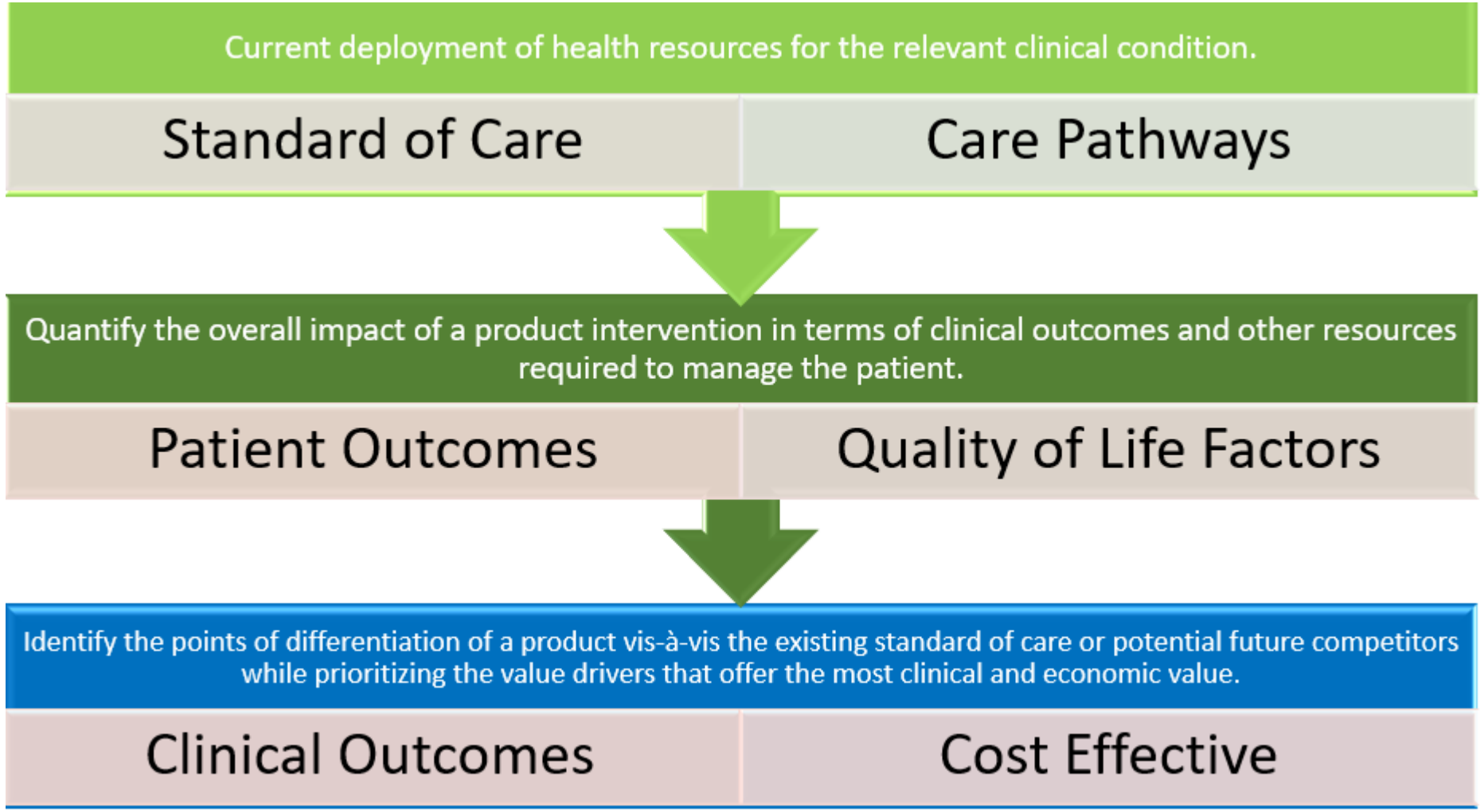
- [ ] Clinical Efficacy and Effectiveness
- [ ] Clinical Utility
- [ ] Clinical Efficacy, Effectiveness and Utility

*Beware that all medical technology must fit into a benefit category for CMS to reimburse.

Market Access Needs Assessment

- Map Stakeholders
- Understand **opportunities / risks** and **clinical, economic and humanistic value proposition** for **each major stakeholder**
- Provide **evidence-based value** (EbV) input
- Develop arguments for robust **value propositions**
- Identify a **path to routine optimal reimbursement** and **market access** in each target market

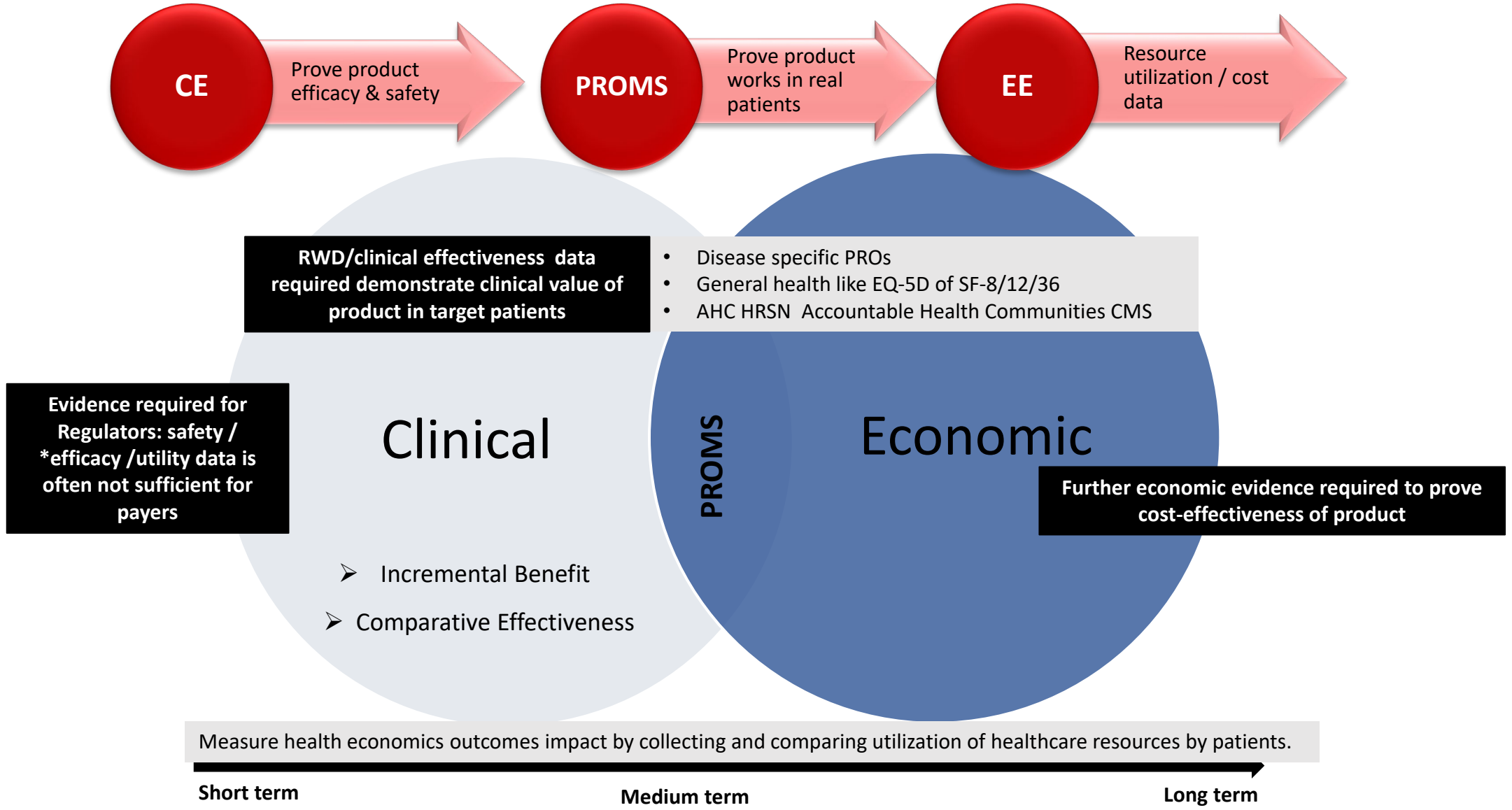
Key Value Drivers



Value Platform

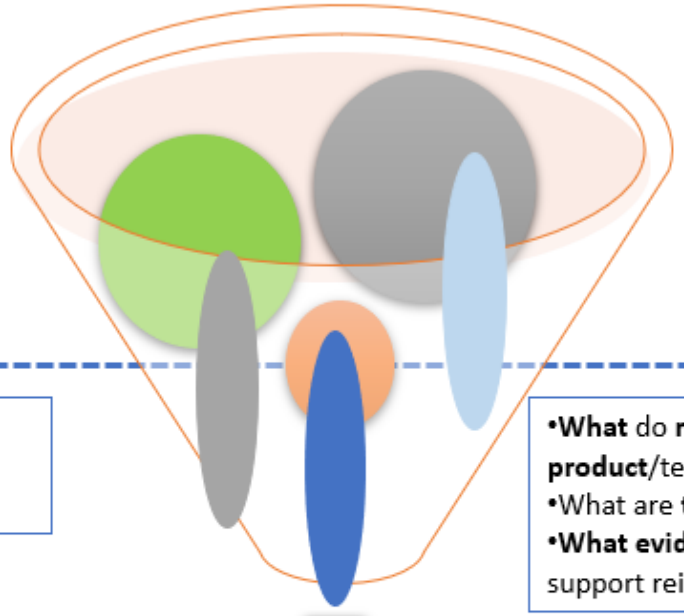
1. VALUE IDENTIFICATION
2. VALUE DETERMINATION
3. VALUE CAPTURE/REALIZATION

Varying Evidence Requirements



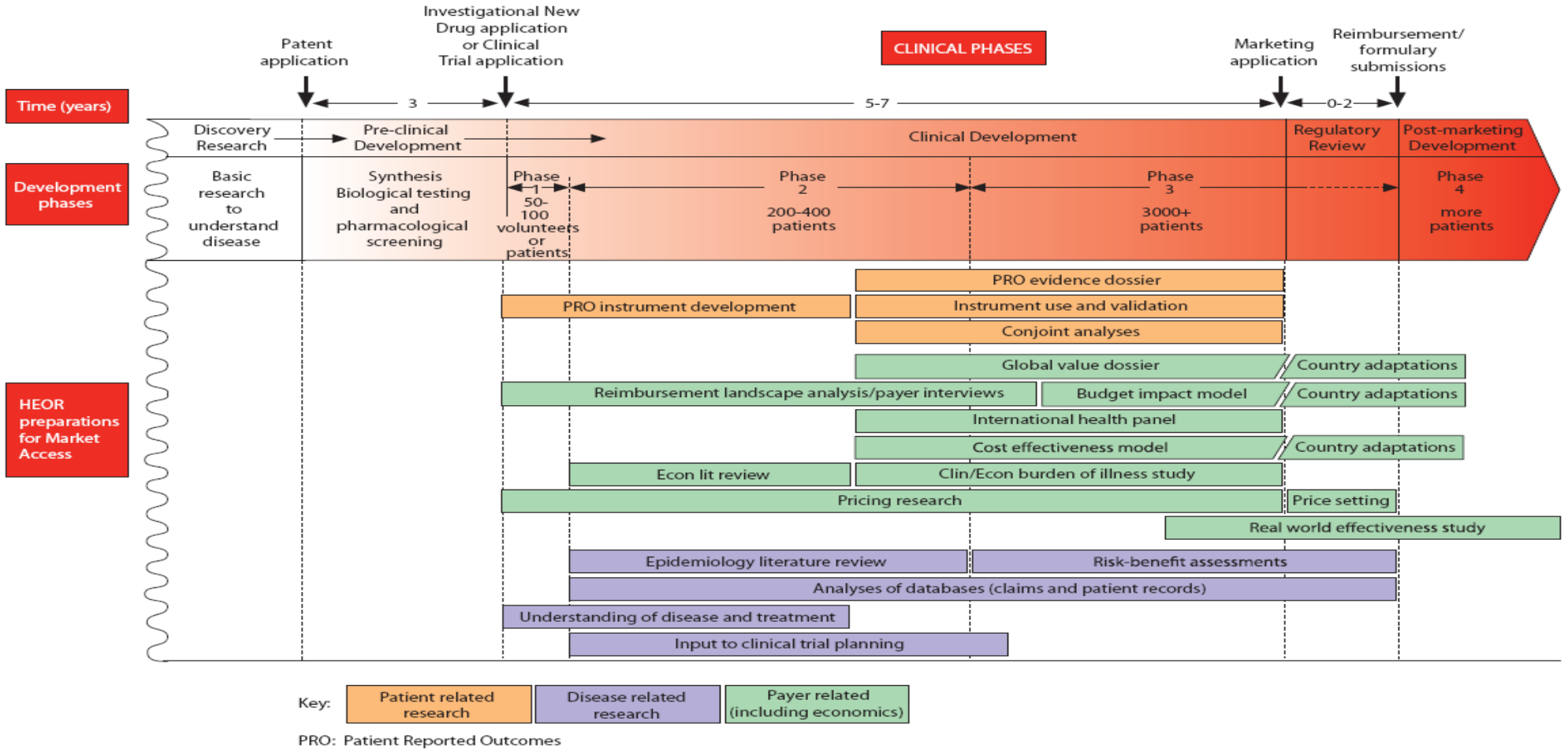
Product pre-concept through commercialization

Life Cycle	Focus
New idea **"Value Identification / Demonstration"**	•Is there **any possibility** of **reimbursement?** • Could **reimbursement** be an **advantage or disadvantage**?
Product development **"Value Determination"**	•**What** do **reimbursement stakeholders think** of the **product**/technology? •What are **their potential value propositions**? •**What evidence** will **need** to be developed to support reimbursement??
Launch / commercialisation **"Value Capture / Realisation"**	•**What** is **the final reimbursement value proposition**? •**What** Market Access (HE&R) **implementation tools** are **required?**



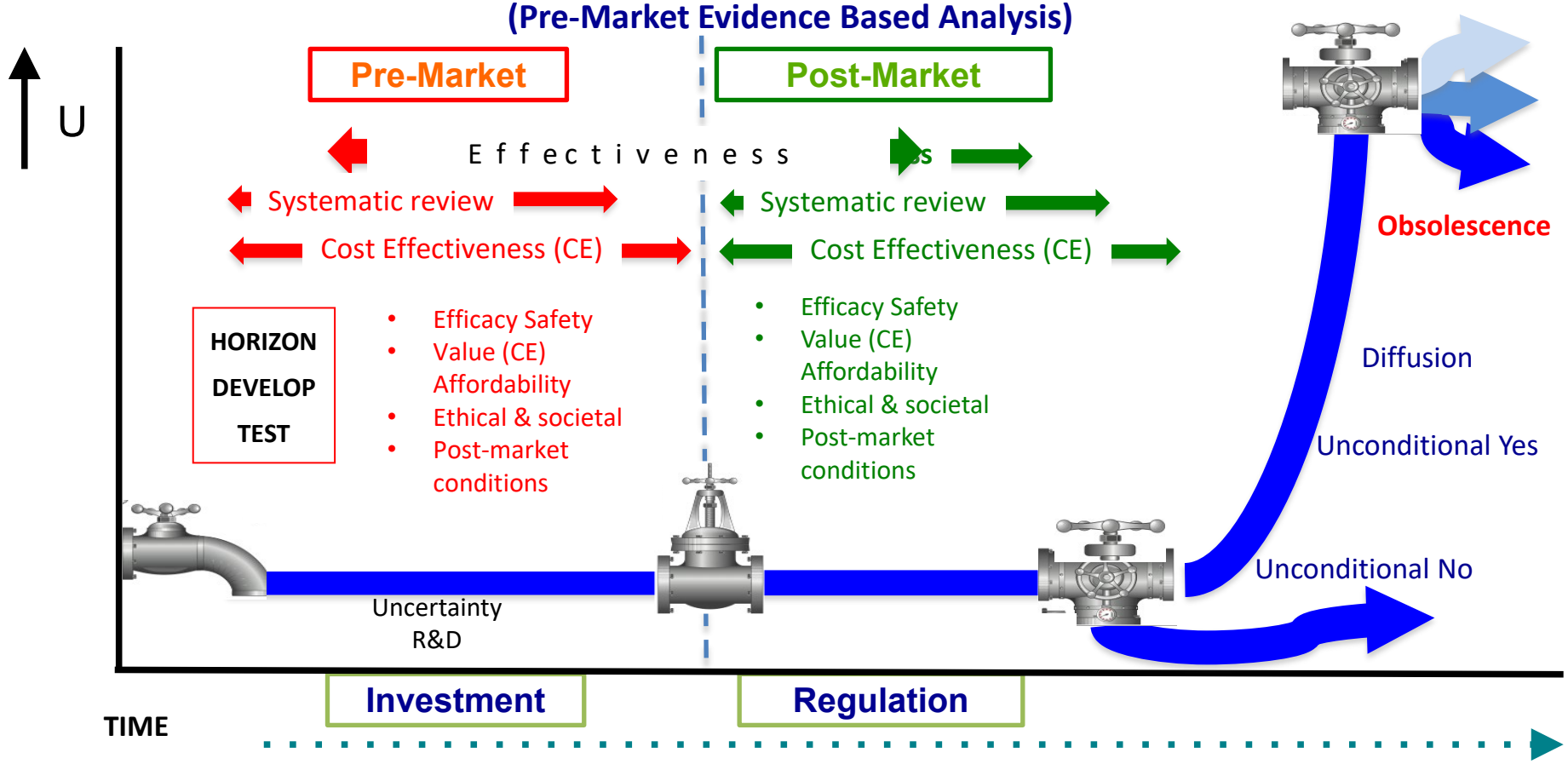
Value communication strategy to relevant stakeholders

Matrix Team Product Life Cycle Plan



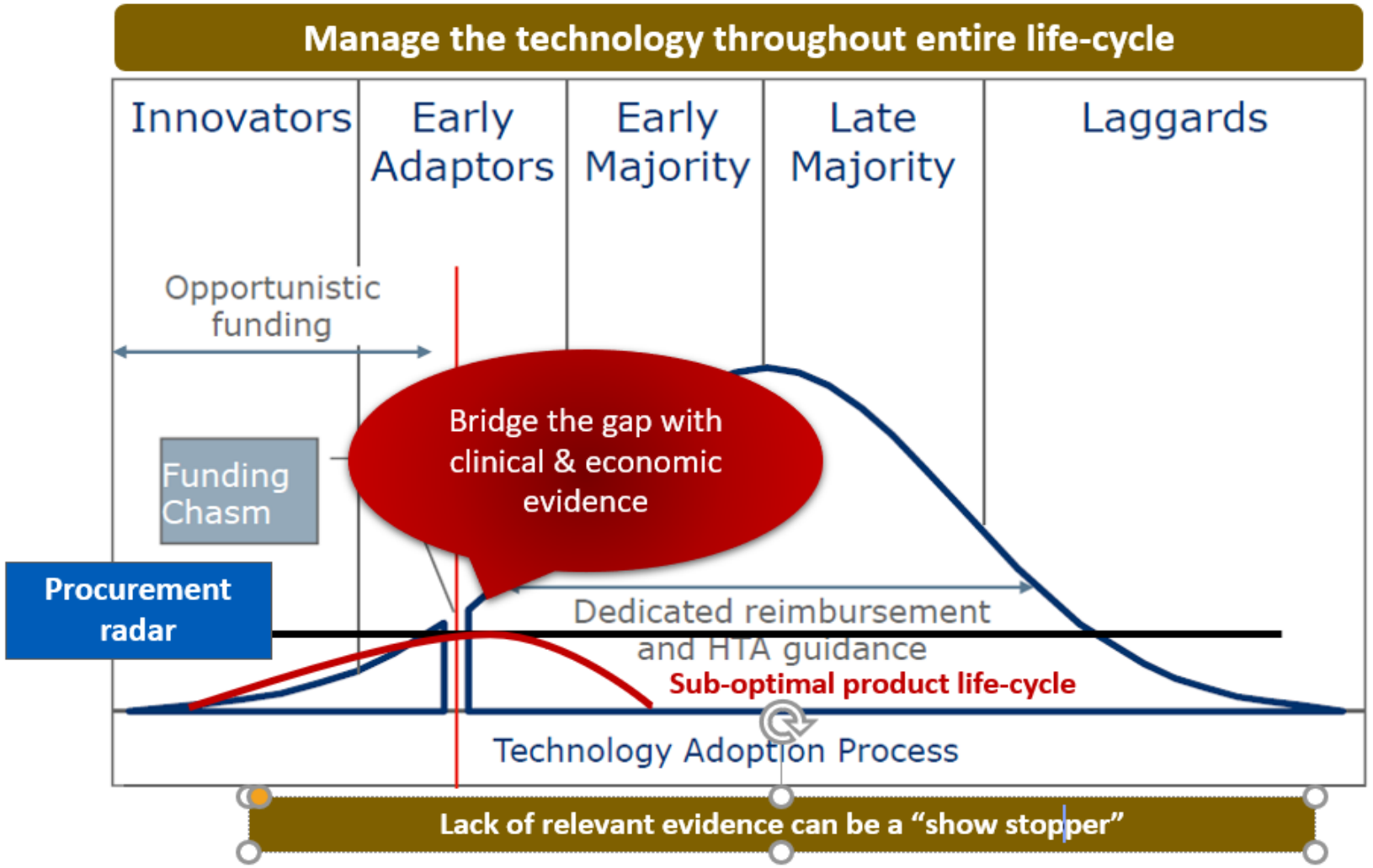
Life-Cycle Diffusion Curve

(Pre-Market Evidence Based Analysis)



MaRS EXCITE

Life Cycle Management



Organize Value Story

Value Communication Tools

Key RESOURCES

1. Clinical Keyword Guide
2. Clinical Summary
3. Clinical Dossier
4. Global Value Dossier
5. Value Communication Tool

Take Home Messages

- **HEMA as a catalyst for value generation**
  - Early discussions with key decision makers, assessors, authorities is mandatory for speed to market
  - Focusing on clinical, economic and outcomes evidence a **MUST**
  - Identification of core value messages that are consistent, but take market and stakeholder nuances into consideration
  - Early involvement and regional focus will accelerate time to peak sales globally when product life-cycle management is considered across markets
  - Endorsing multidisciplinary team work is **KEY**

Think GLOBAL, act LOCAL

Take Home Messages

- **Market differences and requirements prevent single HEMA approach**
  - Funding & reimbursement differences need to be understood to ensure sustainable MA
  - Varying “Decision Makers” & “Stakeholders” with differing needs
  - Different healthcare system dynamics (hospital funding, HC financing, HTAs, procurement mechanisms and evidence requirements)

- **Identification of needs & requirements of various stakeholders**
  - Essential to long-term sustainability of market share
  - Generate “right” evidence to create relevant value propositions

Take Home Messages

HEMA team needs specific skill set

- Clinical Trial Design (Statistical Analysis)
- Publishing Management (Internal and External)
- Clinical Evidence Organization
- Clinical Dossier Preparation
- IIT Approval Process

Medical Affairs

- Clinical Specialists shift to MSL
- Slide Deck preparation
- KOL and Speaker Development
- IIT Solicitation (as needed per clinical evidence plan)

Shift in Marketing/Sales Leadership

- Market Research (Health Systems, Payer Mix, Physician employment)
- F/B to Value
- Segment Marketing Messaging by Customer
- Price should correlate with Outcomes evidence
- Stop selling Reimbursement

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Communicating Effectiveness & Value: Making the Case for Coverage

AdvaMed's Reimbursement 201

Michael D. Miller, MD

Health Care & Life Sciences Consultant

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April [illegible]2023

Overview & Agenda

1. **Introduction & Goals**
2. **Overview/Review**
   - **Different Types of Data & Evidence**
   - **Matching Type of Technology with Type of Evidence and How Data is Generated**
   - **How Digital Health, AI, RWE, PRO are changing the MedTech landscape for evidence development and value propositions**
   - **"Value Frameworks"**
3. **What will be different after the COVID pandemic, i.e., SARS-CoV-2 is endemic**
4. **Different Types of Stakeholders & Decision Makers**
5. **Changing Landscape for Evidence to Make the Case for Coverage+**
6. **How to Communicate Information about Effectiveness and Value**
7. **Conclusions & Recommendations**
8. **Q&A**

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1. Introduction & Goals

- Me and AdvaMed's Value Work
  - I'm a surgeon by original training and inclination
  - Focus on Practical, Not Theoretical
- This Will Be a Different Sort of Presentation/Discussion
- Goals for Today
  - Brief Overview of Data and Evidence
  - Insights About Effectively Communicating Data and Evidence
    - To whom? (what population?)
    - For what purposes?

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2. Overview/Review

- **Different Types of Data & Evidence**
- **Matching Type of Technology with Type of Evidence and How Data is Generated**
- **How Real-World Evidence (RWE), Patient Reported Outcomes (PROs) and Digital Health are changing the MedTech landscape for evidence development and value propositions**
- **“Value Frameworks” & HTA Hurdles**

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Poll #1: Do you know about this paper?

- ❑ **A. Have Read It**
- ❑ **B. Know About It, Not Read**
- ❑ **C. Didn't Know About It**
- ❑ **D. Not Sure/Don't Know**

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MedTech Is "Different" than BioPharma

1. Diversity of Modalities
2. Speed of Innovation
3. Connections to Systems of Care
4. Learning Curve
5. Patient Use and Interaction

Engineering v. Primary Research

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Different Types of Data & Evidence

- Double Blinded Clinical Trials
- Registries
- Observational Studies
  - Prospective, Retrospective
  - Matched, Data Sources
- Case Studies
- Real World
- Patient-Reported
- Digital Apps

Engineering v. Primary Research

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Matching Technology and Data

- What types of data and evidence are appropriate for the specific medical technology?
- What is the relevant time-frame?
- What types of data and evidence are important?
  - To whom? (what population?)
  - For what purposes?

  "Data and evidence for medical technologies are used for different purposes, including regulatory approval, coverage and payment policies, and clinical guidelines or guidance."

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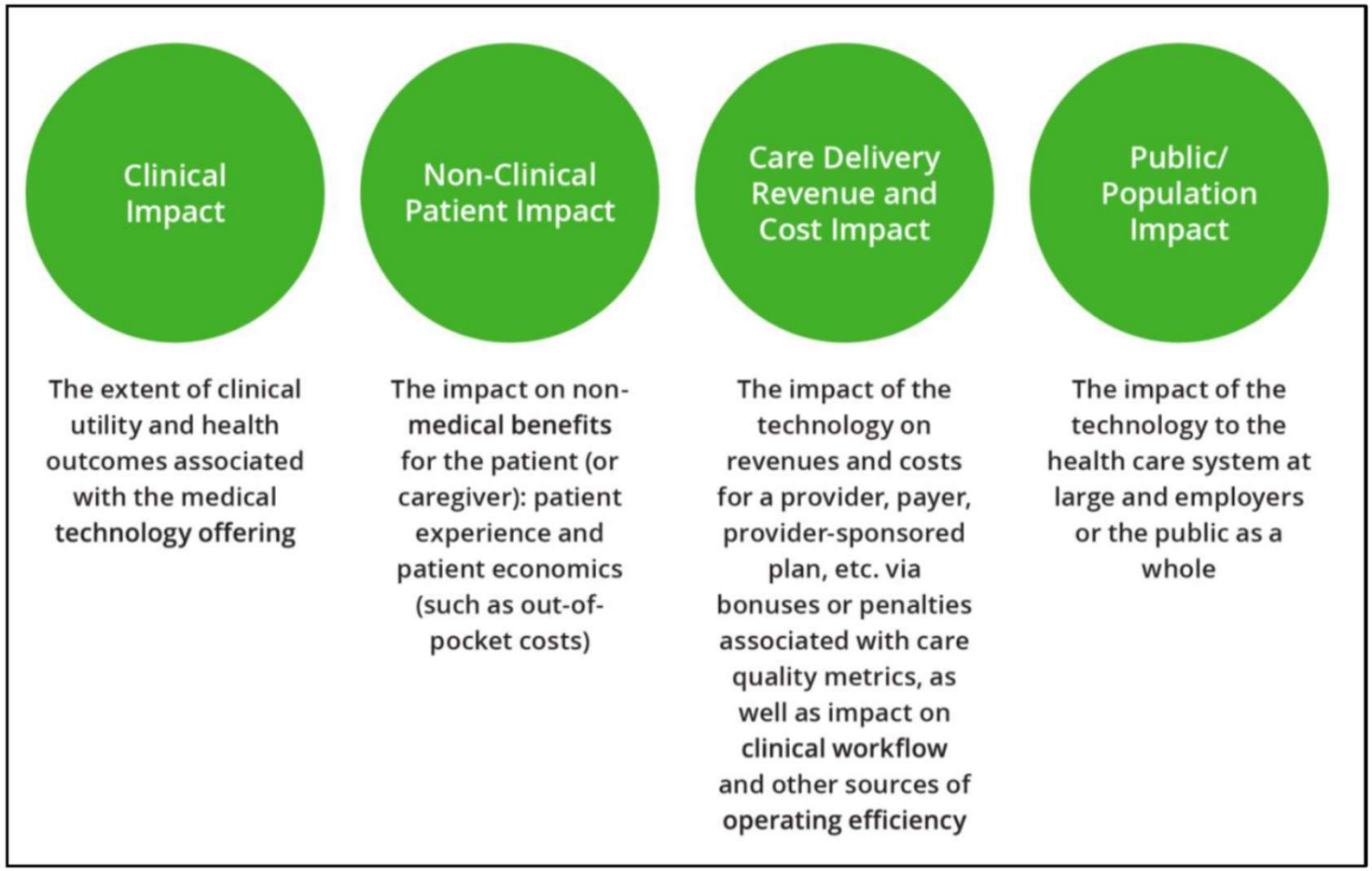
Value Drivers for MedTech

Moving from Volume (Activity) based financing to Value (Outcomes)



Derived from "A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystem, co-developed with Deloitte Consulting LLP, May 2017.

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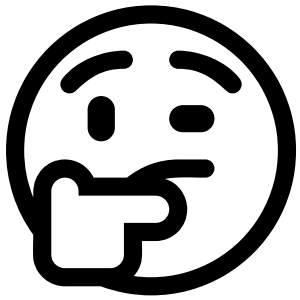
Poll #2: Biggest Changes for MedTech in Past 2 to 3 Years? (Answer Any/All)

- ❑ **A. Digital Health**
- ❑ **B. AI**
- ❑ **C. RWE**
- ❑ **D. PROs**
- ❑ **E. Value Frameworks & HTA Reimbursement Hurdles**
- ❑ **F. Other**



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Digital Health and RWE Changing Landscape for MedTech

- New Types of Data
- New Configuration of Landscape

- New Opportunities
  - **Use of RWE for Coverage and Reimbursement?**
    (Reasonable and Necessary)
- New Challenges
  - **Use of RWE for Regulatory Approvals???**
    (Safe and Effective)

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Value Frameworks

- HTA “Value Assessments”
  - UK has NICE
  - In the US
    - Every Major Payor + VA + Medicare
    - ICER

- **Not “Alternative Facts,”**
  But “Alternate” Algorithms, Formulas, Modeling, Projections, Assumptions etc…
- About both clinical and cost effectiveness

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Poll #3: Biggest Changes In My Company – Past 2 or 3 Years (Answer Any/All)



- ❑ **A. Use of Digital Health in Products or Services**
- ❑ **B. AI in Products or Services**
- ❑ **C. RWE to Improve Products, Services or Value Prop**
- ❑ **D. PROs to Improve Products, Services or Value Prop**
- ❑ **E. Value Frameworks & HTA Reimbursement Hurdles are Hurting Our Business**
- ❑ **F. Other**

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3. After COVID Changes

- Research Landscape Changed DRAMATICALLY During COVID
  - Regulatory Agencies Adapted
  - Payers Adapted for Care Delivery, e.g., Telemedicine
- Expect research flexibility (e.g., sites of trial data collection and remote), but only to the extent that it can provide robust, assured, and valid data.
- Patient Expectations To be Different
- **More business meetings and presentations likely to continue to be virtual – a.k.a., "zoom meetings"**
- **More Anti-Science and Alternative Facts**
  - **Words Have Meaning – or least they used to……**

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Poll #4: Misinformation

Have you run into misinformation about your products or company – or other MedTech products – in the past 2 years?

- ❑ **A. Yes – We have always had some of that, but it's about the same.**
- ❑ **B. Yes – It has increased in the past 2 years.**
- ❑ **C. No**
- ❑ **D. Don't Know/Not Sure**

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4. Different Types of Stakeholders and Decision Makers

- Clinicians
- Clinicians (at Financial Risk)
- Hospitals/Health Systems
- Hospitals/Health Systems (at Financial Risk)
- Insurance Companies
- Self-Insured Employers
- Government Payers
  - US
  - Other Countries
- Patients

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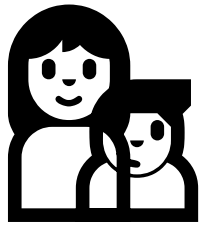
Poll #5: Specific Populations

Does your product or service have a significant use for inpatient pediatric care?



- ❑ **A. Why are you asking that?**
- ❑ **B. No**
- ❑ **C. Don’t Know/Not Sure**

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5. Changing Landscape for Evidence to Make the Case for Coverage+

- More At Risk Clinicians and Providers
  - **What is the future of MA?**
- More APMs with New Variations
- More RWE and Data
- Patient Perspectives More Important
- Post-COVID???

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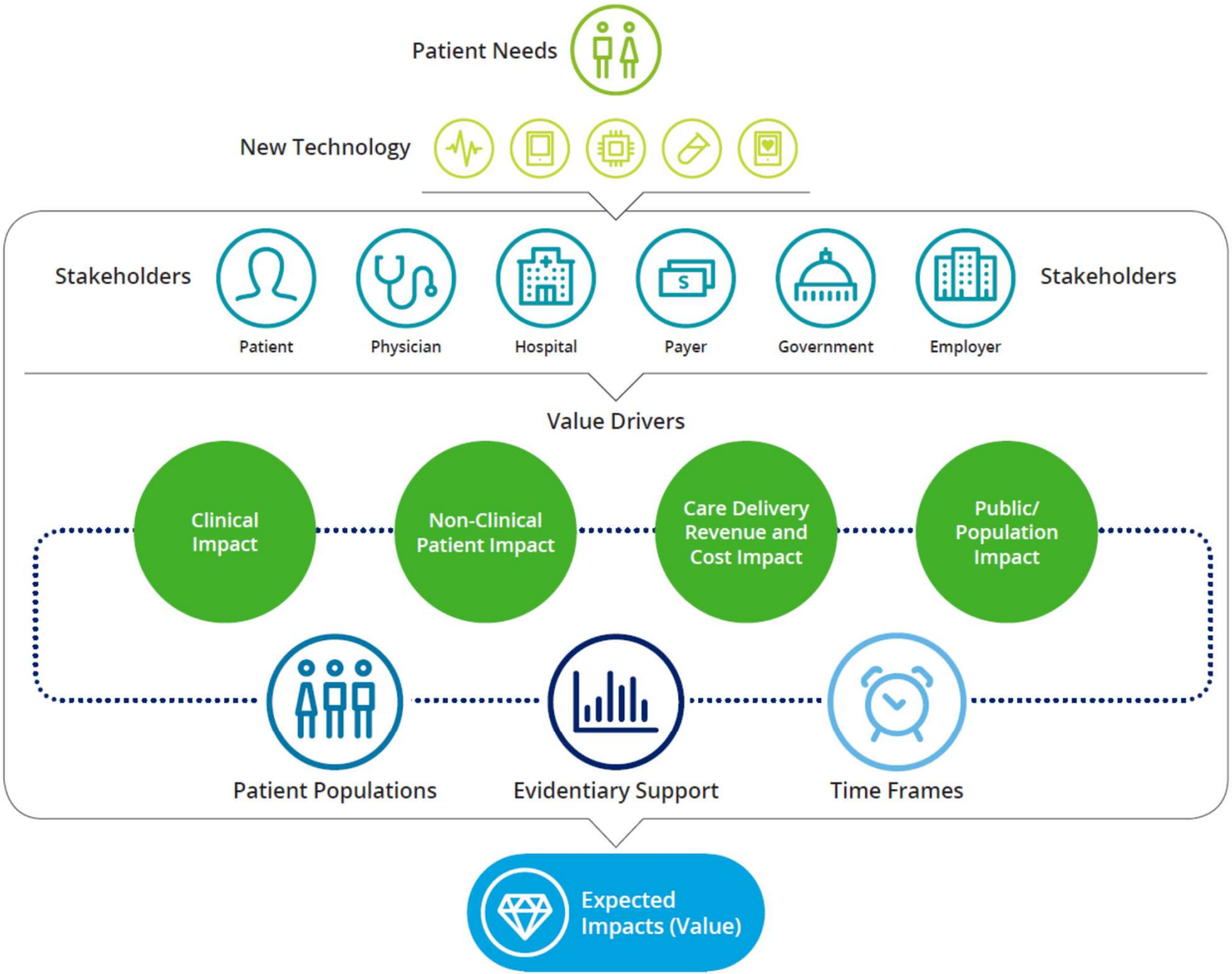

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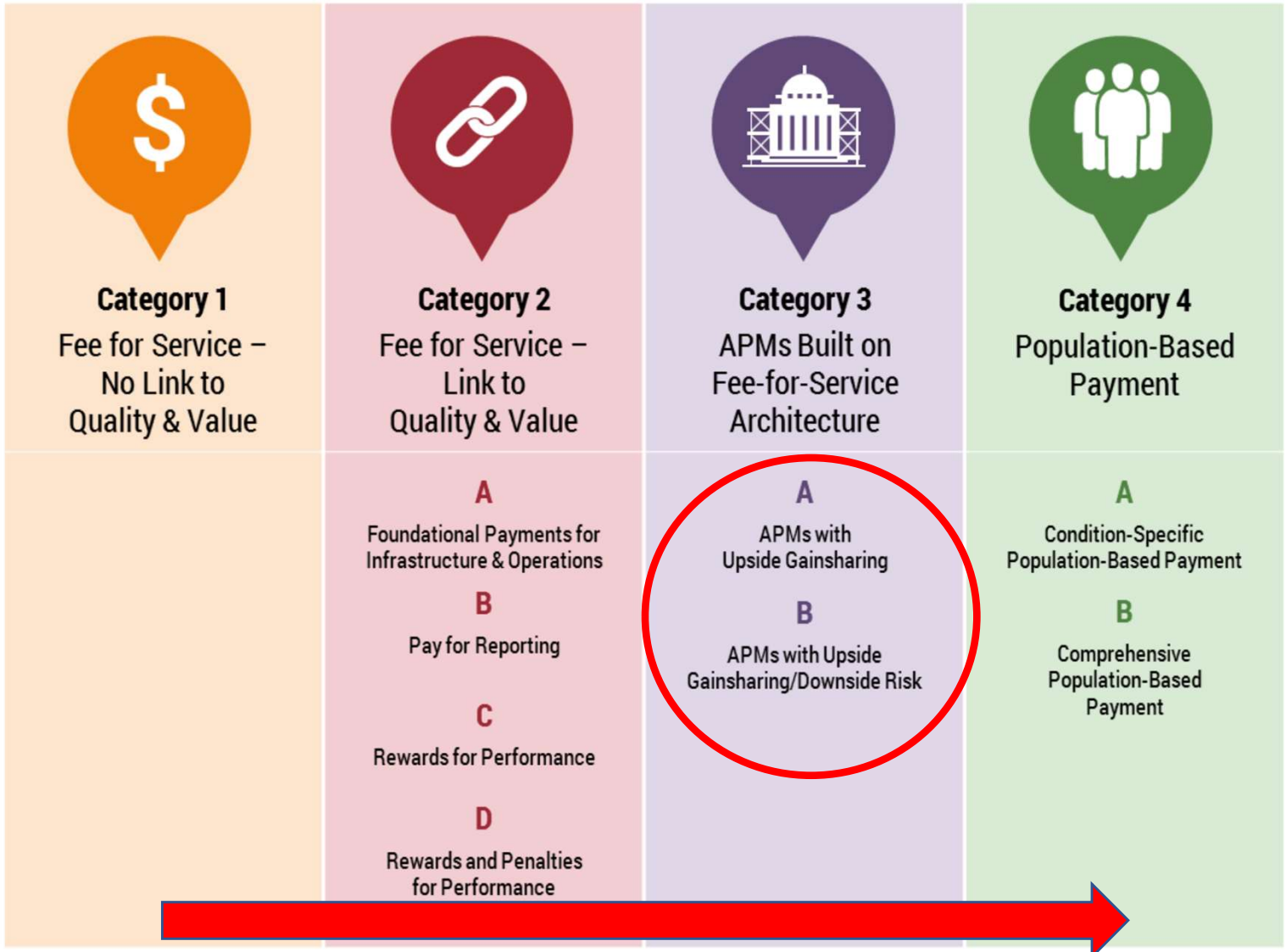
Figure 1. APM Framework (At-A-Glance)



From HCP-LAN " ALTERNATIVE PAYMENT MODEL (APM) FRAMEWORK, Final White Paper," 1/12/2016

Assumption of Risk Connected to Trust

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6. Communicating Effectiveness and Value

Knowledge That Cannot Be Communicated is Worthless

- Communications about value of innovations is about the **content** and **"language"** of the message, **who** is delivering it, **how** it is delivered, and how all of that is **matched** to the audience and their interest(s)
- Who, What, When, Why and How

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6b. Communicating Effectiveness and Value

Knowledge That Cannot Be Communicated is Worthless

- Who is the Audience? (which Stakeholders)
- What Population(s) Do They Care About?
- **Why do they Care: How Are They Incentivized?** (Silo?, Global?, APM, Up/Down At-Risk?)
- How Sophisticated Are They in Their Coverage Arrangements? (Do they have outcomes based contracts?)

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6c. Communicating Effectiveness and Value (One size doesn't fit all!)

What Drives The (post-approval) Clinical/Economic Decision?

- **Use** (Clinicians, Patients, Caregivers)
- **Purchase** (Hospitals/Systems, Clinicians, Patients, Caregivers)
- **Coverage** (Plans, Regulators, at Risk Providers)
- **Reimbursement** (Public and Private Plans)

Put yourself in the stakeholders' shoes and understand the decisions they need to make for the specific technology, for their population & their time-frame of concern.

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Rogers' 5 Factors for Adoption of Innovations

- **Relative Advantage**
- **Compatibility**
- **Simplicity**
- **Observability**
- **Trialability**

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6d. Communicating Effectiveness and Value

Pre-Meeting Assessment:

- **Set Goals for the Meeting. What do you want to accomplish?** (Yogi Berra…..)
- What Is Your Relationship With the Decision Maker?
- **Do They Trust You? Do They Trust Your Data? (and vice versa)**
- **What are the 4 WORST Words to Start a Meeting Where You want to Make a Transaction?**

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6e. Communicating Effectiveness and Value

Preparing for the Meeting:

- **Practice Like You Present**

- **Be Prepared To Adapt and Respond – Be Coachable**

- **Put Yourself In Your Audiences Shoes….. What Do They Want & Need? What Is Their Population?**
- **How Are They Viewing Effectiveness?**
- **What is their Value Paradigm and Financial Incentives?**

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6f. Communicating Effectiveness and Value

Post-Meeting:

- **Review and Follow-Up**
- **“No” Means “Not Yet”**
- **If you don’t ask, the answer is always “No”**
- **Be a Baseball Hitter, Not a Airplane Pilot**

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Poll #5: Case Studies, Exercise or Q&A?

- ❑ **A. General Q&A?**
- ❑ **B. Communications Exercises**
- ❑ **C. Case Study**
- ❑ **D. Don’t Know/Not Sure**

- ❑ **E. WHAT? I was asleep, or browsing the web….**

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Exercise

Need a Volunteer….

1. Name a disease/condition
2. Describe a Treatment
3. What is the optimal outcome from that Treatment?
4. What is the predominant population for that disease/condition?
5. Who are the dominant payer(s) for that population?
6. How do those payers operate, i.e., their landscape?
7. What is your relationship with that payer/decider?

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7. Conclusions

1. Evidence and Data Generation

- **Appropriate for that technology** and the needs of the relevant stakeholders.
- Research should be done efficiently
- The data and evidence should match the medical technology and its risks, expected benefits, uncertainties, differences from existing options, and be **aligned with the intended use of the evidence**

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7. Conclusions

2. Assessment of Evidence

- Analysis of the evidence must be appropriate for both the type of evidence and the aspects of the technology, and should not disregard evidence if it is not from controlled or blinded trials
- Clinical and cost evaluations must be done in the context of **specific patient populations**

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7. Conclusions

3. Decision-Making Using Evidence

- "One size fits all" approaches are not appropriate
- Evaluations of cost should be conducted within the scope of the organization's specific patient populations, from specific stakeholder perspectives, (e.g., the patient), and within timeframes appropriate for the technology
- Decisions about types of evidence and analytical methods should be done in **collaboration with all key stakeholders**

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7b. Recommendations

4. Customize/Individualize Presentation of Data and Evidence to the Audience

- Establish Goals for Meeting
- **Frame Message to the Audience and Population That They Care About** (Clinical and Economic Outcomes)
- Engaged with Trust & Authentic Messaging
- **Know What You Know & What You Don't Know**
- Be Prepared, Practice, and Be Coached
- **Understand the Differences Between In-Person and Virtual Meetings**

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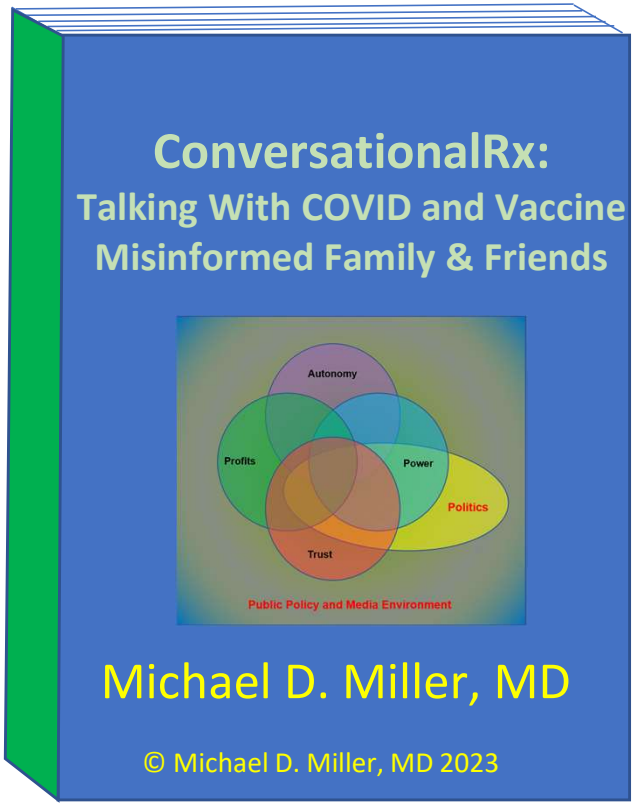
Thank You

Q & A



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THE NICKLES GROUP LLC

MedTech Coverage, Coding, & Reimbursement Workshop
Healthcare on the Hill

Brett Baker

April 26, 2023

Private and Confidential

Healthcare on the Hill

Objectives

- Overview of key players and committees
- Understand the current legislative landscape for Medicare policy
- Identify key opportunities and challenges for advancing healthcare policies on the Hill

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The Nickles Group

Who We Are

- The Nickles Group (TNG) has provided strategic advice and counsel, legislative and Administrative outreach, and unmatched service to our clients since 2005.
- Our team is equipped with decades of experience in the U.S. Senate, the U.S. House and the Administration, spanning four different Administrations: Bush, Obama, Trump, Biden.
- Our firm strives for, and maintains, many long-term partnerships.
- We work proactively, and collaboratively, with our clients to accomplish their advocacy goals.

What We Stand For

- While the political landscape is everchanging, the outstanding quality of our firm and relentless commitment to our clients remains the same.
- Much like Senator Nickles' commitment to working across the aisle throughout his career in the U.S. Senate, our firm is committed to working in a bipartisan manner to achieve optimal results for our clients.

Brett Baker

- **U.S. Senate Committee on Finance**, Health Policy Director, 2020-2021; Senior Health Policy Advisor, 2015-2019
  - Worked under three different leaders, two Chairmen—Senators Orrin Hatch (R-UT), Chuck Grassley (R-IA)—and Ranking Member Mike Crapo (R-ID).
  - Negotiated the most significant Medicare bills that passed Congress during his tenure, including COVID-19 relief efforts.
  - Played an integral role in informing the debate on key policy issues, including prescription drugs and Medicare Advantage.
- **U.S. House Committee on Ways and Means**, Professional Staff Member, 2011-2015
  - Worked under two different Chairman—Representatives Dave Camp (R-MI) and Paul Ryan (R-WI).
  - Led effort to repeal the Medicare Sustainable Growth Rate formula and reform the physician payment system.
  - Shaped policies in additional health care sectors, including the Medicare system for paying hospitals, providers administering outpatient prescription drugs, dialysis facilities, and clinical laboratories.
- **The American College of Physicians**, Regulatory Affairs Director, 1995-2011
  - Used expertise on payment issues to advocate for internists with CMS.

BRETT BAKER

PARTNER

THE NICKLES GROUP LLC

TNG Core Health Care Team

SEN. DON NICKLES

CHAIRMAN & CEO

MARY BETH SAVARY TAYLOR

PRESIDENT

GREG D'ANGELO

PARTNER

BRETT BAKER

PARTNER

- Over 100 years of combined health care policy expertise.
- Keen familiarity with Capitol Hill, the White House, and federal agencies.
- Strong understanding of the broader health care landscape, including experience working for companies and associations in a cross-section of the health care industry.

Key players and committees

House (Republican control)

- Ways & Means Committee
- Energy & Commerce Committee
- Leadership
- Members with strong stakeholder presence
- Congressional caucuses

Senate (Democrats control)

- Finance Committee
- Health, Education, Labor, & Pensions Committee
- Leadership
- Members with strong stakeholder presence

Biden Administration

- CMS, HHS, White House
- Administration influence on legislation
- Congress influence regulatory decision

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Current legislative landscape for Medicare policy

Landscape is Bleak

- Divided government in lead up to Presidential election
- Need to raise the debt limit
- Republican insistence on reducing spending
- Medicare spending reductions off-the-table, but tenuously

But Some Hope

- "Must-do" policies with bipartisan support
  - Medicare "extenders"
  - Public health programs, e.g., Community Health Centers funding, reauthorization
  - Pandemic and All-Hazards Preparedness Act reauthorization
  - Opioid use disorder programs reauthorization
- Bipartisan policy areas of interest
  - Address health care workforce shortages
  - Reform Pharmacy Benefit Manager practices
  - Increase transparency and competition

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Opportunities and challenges for advancing healthcare policies

Challenges

- Bleak overall landscape
  - House Republican rigid rules on what gets a vote
  - End-of-year omnibus "Christmas tree" less likely
- Non-partisan scorekeeper, the Congressional Budget Office
- Reaching bipartisan agreement, with Committees often at odds

Opportunities

- Health care policies likely to pass Congress and be signed into law
- Bipartisan interest in policies that reduce spending
  - Can be used to offset cost of policies that increase spending
- Republicans more forward on fostering innovation and drive agenda in House
- Influencing the Administration to secure regulatory wins

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Opportunities and challenges; AdvaMed interest illustrations

Expanding Medicare OPPS/ASC Pass-through

- Policy goal permanently extend from 3 years to 5 years for devices and drugs ➡ One-time two-year extension for drugs paid as a supply (2018)
- Policy goal temporary 5 years of separate payment for drug and device alternative to opioids ➡ 3-year drug and device separate payment with limitations (2022)

PAMA Clinical Lab Fee Schedule Private Payer-Based Rates

- Policy goal major reforms to the PAMA law ➡ Short-term delay in phase-in and new reporting rounds (multiple laws)

Payment for Disposable Negative Pressure Wound Therapy

- Policy goal beneficiary access to more convenient disposable NPWT through home health agency ➡ Fix CMS implementation problems with reduced payment amount (2015, 2022)

Coverage Pathway for Breakthrough Devices

- Policy goal CMS establish Medicare coverage for breakthrough devices, with CMS committing to revise rescinded Trump Administration MCIT rule after bipartisan pressure ➡ ???

Healthcare on the Hill

Comments/Questions