US Digital Health

30 April 2025

Digital Health Commercial Models

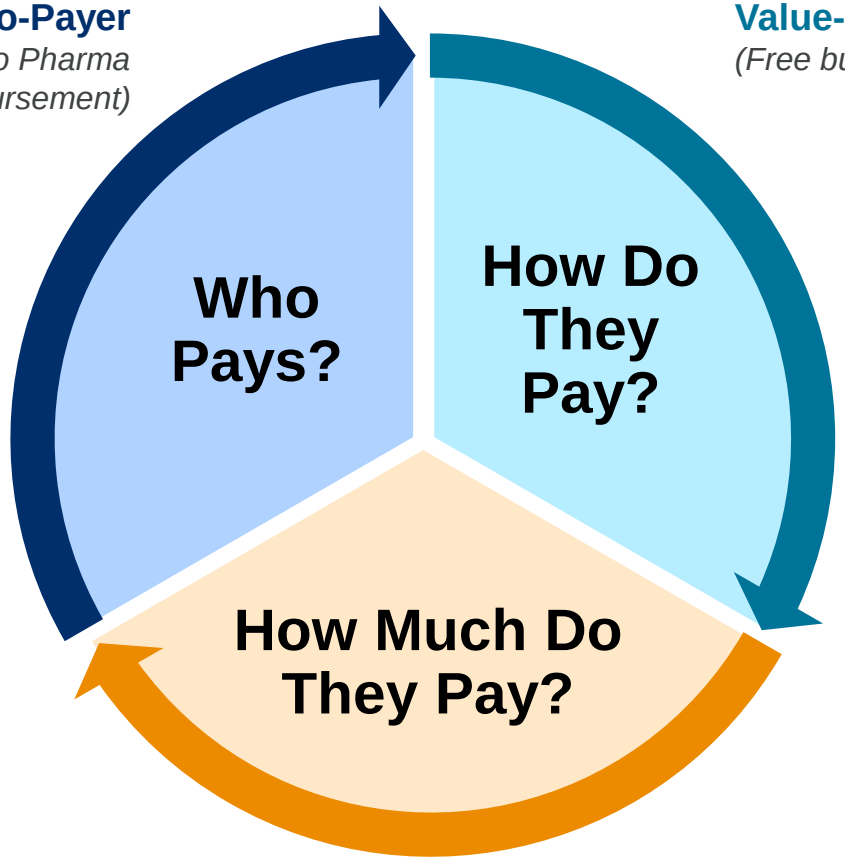
What's my Commercial Model?

A product's reimbursement pathway is inherently linked to its commercial model and, specifically, who pays. There is no single commercial model that clearly generates more revenue and many digital medicine companies pursue multiple commercial models for the same underlying asset.

Business-to-Payer
B2P (Most similar to Pharma Reimbursement)

Business-to-Business
B2B (Provider Organizations/Employers)

Business-to-Consumer
B2C (Cash Pay)



Value-added service
(Free but supports other offerings)

Per Use
Pay as you go

Per Period
Subscription, Episode

One Time
All-you-can-use

Amortize value of generated data

Value Creation
(Outcomes based pricing and actual cost of care-based pricing)

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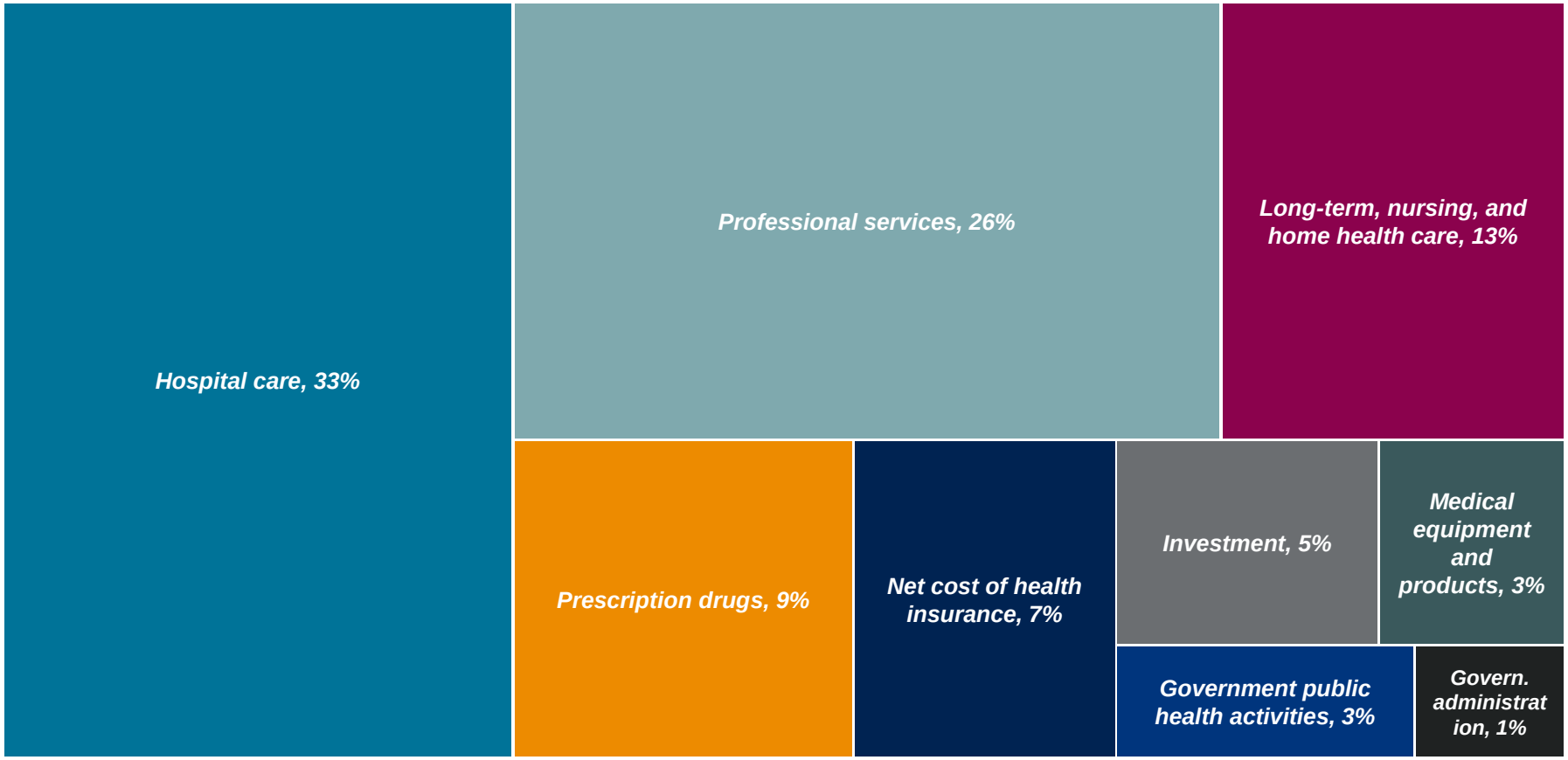
Where is money spent?

Breakdown of United States National Health-Care Expenditures by Type



Source: CMS 2018, The Hamilton Project | Brookings, EVERSANA Analysis. Data from 2018 show that long-term, nursing, and home health care include residential, personal, and home care services, as well as nursing facilities and retirement communities. This category covers expenditures for residential care, ambulance services, nontraditional medical settings (e.g., community centers, schools, military stations), and Medicaid Home and Community-Based Waiver programs. Freestanding nursing and retirement facilities are included, while hospital-based services fall under hospital care. Medical equipment includes both durable and nondurable products.

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The US has various commercial models utilizing private insurance and an evolving framework for government reimbursement

Commercial model	How it Works	Examples
B2C	**Direct to Patient** – Patient pays directly OOP to the Digital Medicine developer. May include prescription via telehealth.	mahana THERAPEUTICS, NOOM, AKILI, Rejoyn™
B2B2C	**Programmatic Spend** – Manufacturer negotiates with private health plans and employer-sponsored Healthcare plans, which then offer the app to members and adjust premiums.	Livongo, NIGHTWARE, omada
	Provider Billing – Manufacturer sells to providers, clinics, hospitals, and IDNs, which then bill insurance for provider time via procedure codes (CPT codes, e.g., RPM, RTM, CCM, etc.)	BrainCheck, Lifescan, HeartCloud, aidoc, Big Health
	Pharma Partnership – Manufacturer partners with pharma who then provides the companion app or patient support app free of charge to patients.	Propeller, Click Therapeutics, PathAI, dario
B2P	**Virtual Care** – Manufacturer serves as a provider and bills insurance (govt, private) directly for provider time via procedure codes (CPT codes, e.g., RPM, RTM, CCM, telehealth, etc.)	OSHI HEALTH, swing Therapeutics, JOGO, one medical
	Manufacturer Billing on Medical Benefit – Manufacturer obtains HCPCS code and bills insurance (govt, private) directly for use of the app. Lack of benefit category.	AppliedVR, MEDRhythms THERAPY
	Manufacturer Billing on Pharmacy Benefit – Manufacturer negotiates coverage with payers on pharmacy benefit or via digital formulary and bills with a product-specific NDC-like code on compendia.	Abbott, Livongo, Propeller

Digital medicine manufacturer | Doctor | Patients | Hospital | Payers/insurance companies | Pharmaceuticals

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Digital Commercial Models: Who Will Pay for the Product?

There are numerous types of digital health products and several commercial models in the US which determine who pays for the product.

Archetype	Pathway	Minimum Requirements to Compete		
		FDA-Clearance	Prescription	Clinical Evidence
 **Business to Consumer:** Cash Pay	**Direct to Consumer**	**No**	**No**	**No**
 **Business to Business:** Organizational Offering	**Direct to Business** ▪ Paid for by an **employer** to offer to employees ▪ Purchased by a **provider** to offer to patients	**Varies**	**Varies**	**Usually**
	Pharma Partnership ▪ Purchased directly by **Pharma and MedTech**	**Varies**	**Varies**	**Usually**
	Direct Payer Payment ▪ Paid for by payers as part of **programmatic spend**	**Varies**	**Varies**	**Usually**
 **Business to Payer:** Claims-based Reimbursement (Traditional Coverage)	**CPT/HCPCS Code** ▪ Reimbursed through the current CPT/HCPCS code pathway	**Usually**	**Yes**	**Yes**
	UDI/NHRIC Code ▪ Reimbursed through a product-specific reimbursement number	**Usually**	**Yes**	**Yes**
	Virtual Care ▪ Manufacturer serves as a provider and bills insurance directly for provider time via CPT codes	**Usually**	**Yes**	**Yes**

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Regulatory Pathways

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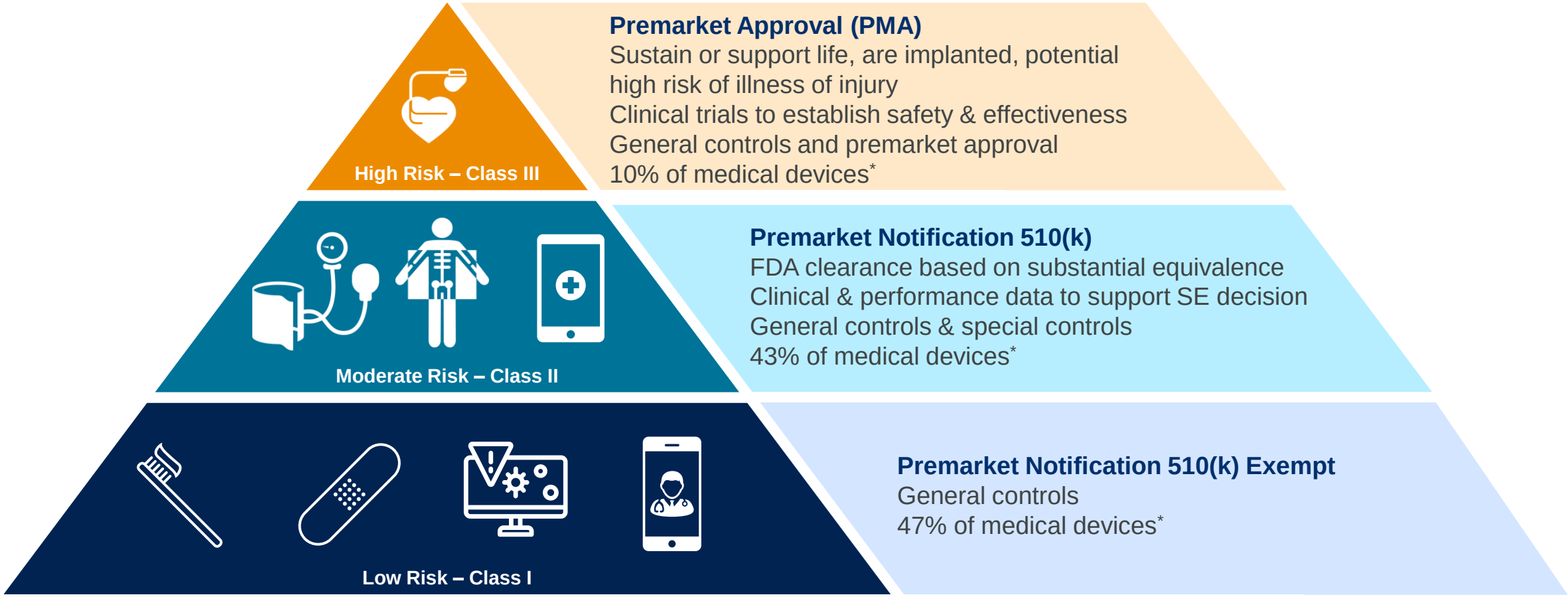
FDA Regulation of Medical Devices

FDA classifies medical devices based on their potential risk to do harm to the user



Premarket Approval (PMA)
Sustain or support life, are implanted, potential high risk of illness of injury
Clinical trials to establish safety & effectiveness
General controls and premarket approval
10% of medical devices*

Premarket Notification 510(k)
FDA clearance based on substantial equivalence
Clinical & performance data to support SE decision
General controls & special controls
43% of medical devices*

Premarket Notification 510(k) Exempt
General controls
47% of medical devices*

* According to FDA, as published on *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing

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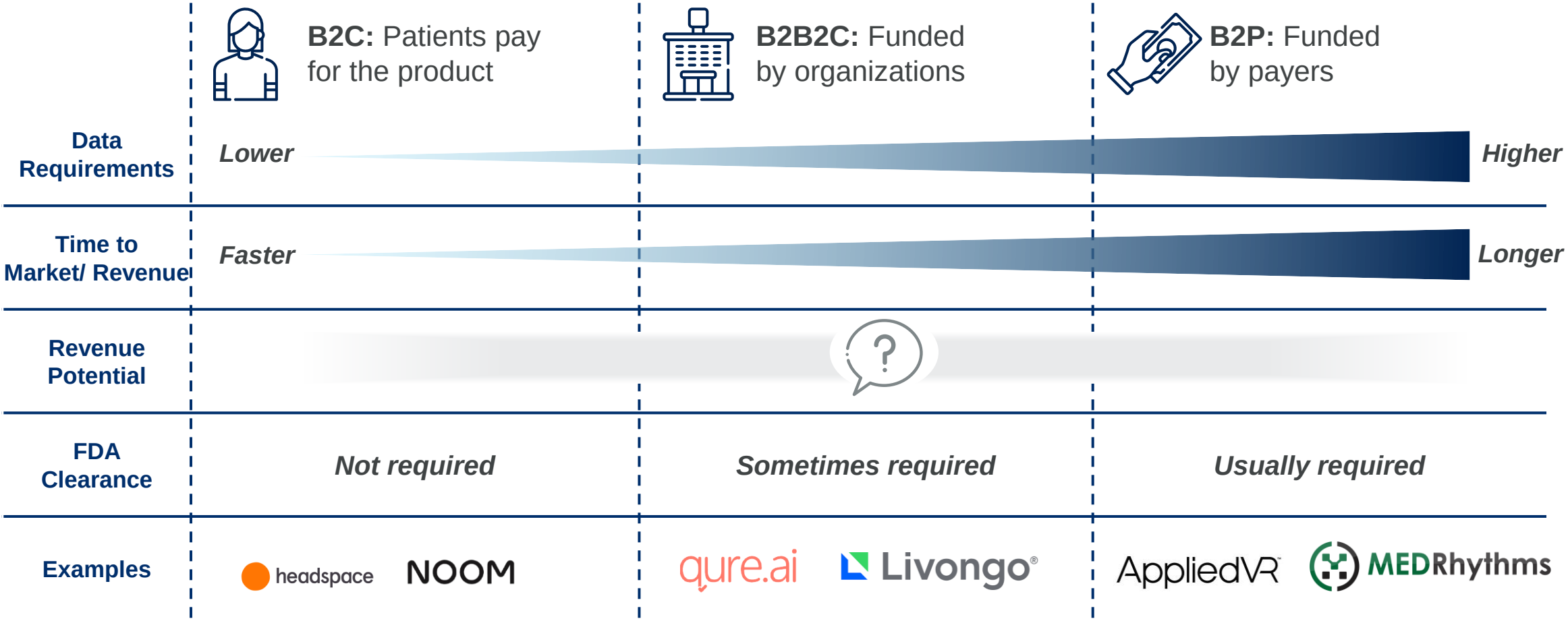
The US has various Commercial Models with different levels of Regulatory and Clinical rigor.



Regulatory pathway for digital health is often a choice!

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FDA Regulatory Oversight of Digital Health

Digital health products require FDA submission based on intended use and risk. Devices with treatment or diagnosis claims likely require a 510(k) or De Novo, which determines their regulatory classification.

N/A	*N/A*	*510(k)*	*De Novo*	*PMA*
Unregulated	**Exempt**	**Premarket Notification**	**Request**	**Premarket Approval**
No FDA oversight. For low-risk products that do not make medical claims and are not classified as medical devices.	**Premarket application not required to market the product.** Manufacturer must register establishment and list its devices with FDA.	Premarket notification is required to demonstrate that the device is **substantially equivalent to a predicate device** already cleared for market. **Clinical data** may be required. 510(k) devices **are cleared, not approved** by FDA.	Submission to demonstrate reasonable assurance of safety and effectiveness for **devices with no legally marketed predicate (SE) device**. A **clinical trial** is generally required. De Novo devices are cleared by FDA	**Most stringent type of marketing application.** Required to demonstrate safety and efficacy when used. A **prospective clinical trial** is generally required. ***FDA approves PMA devices.***
Not Regulated	***Most class I devices Some class II devices***	***Most class II devices***	***Mostly class II devices***	***Mostly class III devices***
NOOM headspace happify HEALTH	oleena CANTAB BrainCheck	Rejoyn Beta Bionics welldoc	PEAR THERAPEUTICS Paige WATCH	BIOTRONIK excellence for life

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Exempt and Unregulated Digital Health Pathways

There are several regulatory pathways for Digital Health products that do not require FDA marketing submissions (510k/De Novo/PMA). Some are still considered medical devices and have reduced regulatory burden, and others are not medical devices.

None — Regulatory Burden — General Controls

Wellness	Enforcement Discretion	Exempt Medical Devices
No FDA oversight. For low-risk products that do not make medical claims and are not classified as medical devices Generally, products intended for: • Maintaining a healthy lifestyle • Reducing disease risk • Behavioral health, diet, exercise	**FDA does not intend to enforce requirements under the FD&C Act.** **Premarket application not required** Examples • Low risk apps for disease-self management • DTx for psychiatric conditions during Covid • Specific products determined by Congress	**Premarket application not required to market the product.** Manufacturer must register establishment and list its devices with FDA and follow General Controls. Examples • Most class I medical devices • Some class II exempt medical devices

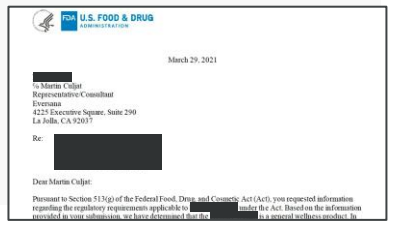
Examples

NOOM

fitbit

headspace

happify™ HEALTH


U.S. FOOD & DRUG ADMINISTRATION

March 29, 2021

Re:

Dear Martin Culjat:

Pursuant to Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), you requested information regarding the regulatory requirements applicable to [redacted] under the Act. Based on the information provided in your submission, we have determined that the [redacted] is a general wellness product. In


VOLUNTIS

ABOUT OUR DIGITAL THERAPEUTICS

VOLUNTIS ANNOUNCES MARKET AUTHORIZATION FOR OLEENA™, FIRST DIGITAL THERAPEUTIC IN ONCOLOGY

Paris, France , 31 July 2019

Voluntis (Euronext Paris, Ticker: VTX - ISIN: FR0004183960), a leader in digital therapeutics, today announced it has successfully completed [redacted] regulatory review of its Oleena™ software for on[redacted] remote patient monitoring. Oleena™ is determin[redacted] enforcement discretion per FDA Guidance.

Livongo by Teladoc Health

omada

Orexo launches digital therapies for depression, alcohol misuse early in US

July 17, 2020

Sweden's Orexo has launched two digital therapies in the US earlier th[redacted] expected, following changes to US regulations that allow early access COVID-19 crisis.

BrainCheck

MEDRhythms

RecoveryPlus.health

Regulatory status of these pathways can be confirmed with 513(g) submission to FDA

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Digital Diagnostics: Top 10 Regulatory Challenges

Digital diagnostics have a diversity of regulations and product codes, and as a result more diversity of questions and challenges.

1. Financing to support clinical validation
2. Understanding regulatory logic and communication
3. Regulatory pathway
4. Regulatory impacts to product lifecycle
5. Statistics
6. Clinical data requirements
7. Knowing when to push boundaries with FDA
8. Executing a clinical performance study
9. Training sets
10. Change control boundaries

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Digital Therapeutics: Top 10 Regulatory Challenges

In the digital therapeutics world, almost all of the most daunting regulatory challenges are related to planning and execution of the pivotal trial.

1. Financing to support a pivotal trial
2. Control condition
3. Engagement + Drop Off
4. Meeting endpoints
5. Aligning regulatory and reimbursement goals
6. Clinical trial execution
7. Negative commercial implications of label
8. Enrollment
9. Failure to prespecify success criteria
10. Everything else: Regulatory pathway, quality, design control, cybersecurity, AI change control, etc.

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Market Access and Reimbursement

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US Market Access Elements: Drugs vs. Digital

	Coding	Coverage	Reimbursement
Drugs	• Automatic National Drug Code number upon FDA approval • If physician-administered, may need Healthcare Common Procedural Coding System (HCPCS) code in addition to NDC assignment	• Customarily quick (0-6 months) post approval • Management may include prior authorization, step edits, formulary placement with high copays	• Payment is net of rebates or discounts • Net price can be negotiated with manufacturer, except when prohibited by CMS • Patient out-of-pocket cost determined by formulary placement and plan, usually pre-deductible
Digital	• New devices should be evaluated to determine whether they can bill under an existing code • If new code is needed, manufacturer applies to CMS or AMA and process takes months to years • Most devices can bill under a miscellaneous code immediately post FDA clearance	• Typically denied until sufficient clinical and economic evidence is available (this may require multiple, independent peer-reviewed publications) • Each payer makes independent decision • Widespread coverage typically takes years but is not guaranteed	• There is no defined benefit category for SaMD by CMS, which could be barrier to reimbursement; note the DTx with hardware could fit into traditional medical device or DME category as standalone piece of hardware or software in a device • Reimbursement level is determined by payer and may be substantially lower than manufacturer price • Patient out-of-pocket cost is often post-deductible and 20% coinsurance

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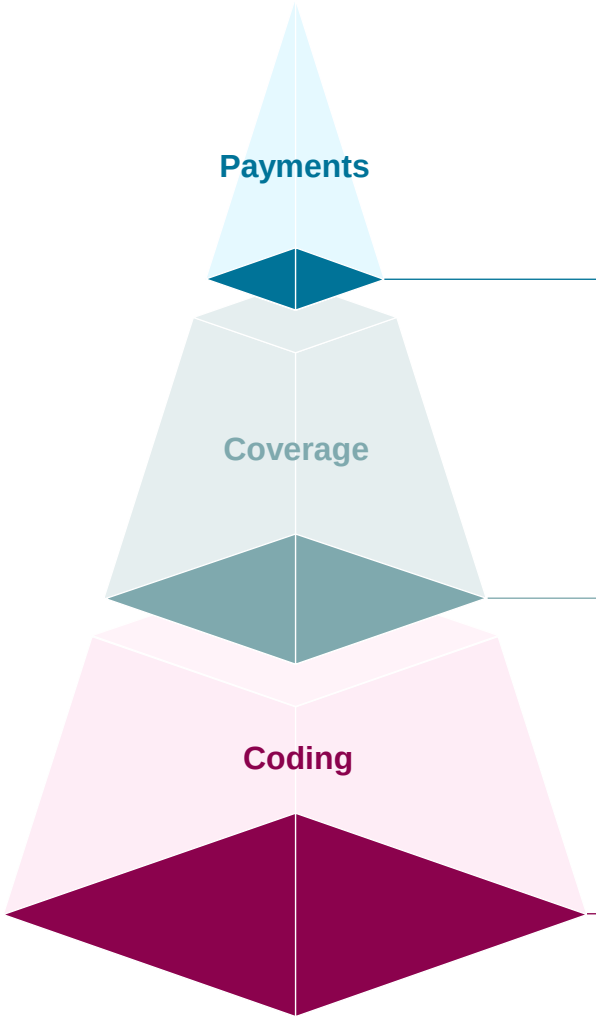
Reimbursement is Built on a Foundation of Coding, Coverage, and Payments



Payments

- Describes who is paid, and how much.
- Payment typically varies depending on the setting where the service is provided.

- Outpatient hospital (HOPD) payments are based on codes grouped into **Ambulatory Payment Classifications (APC) (often as % of APC)** and **inpatient hospital payments** are based on Diagnostic-Relating Groups (DRGs)
- Physician payments for **CPT and HCPCS codes** are often based on the Medicare Physician Fee Schedule (MPFS)

Coverage

- Determines if a technology or procedure **will be reimbursed, and under what conditions**.

- CMS may set **national policies (NCDs)** that apply to the whole country, or Medicare Administrative Contractors (MACs) can make separate local coverage decisions **(LCDs)** for their regions
- Medicaid and private payers **can establish their own coverage policies**, which may or may not align with Medicare policies

Coding

- Serves as the **language of reimbursement**.
- Tells a payer exactly **what was done, how it was done, and why**.

- Patient diagnoses are described using **ICD-10-CM (diagnosis) codes.**
- Procedures, services, products, and supplies are described using **HCPCS and CPT codes**

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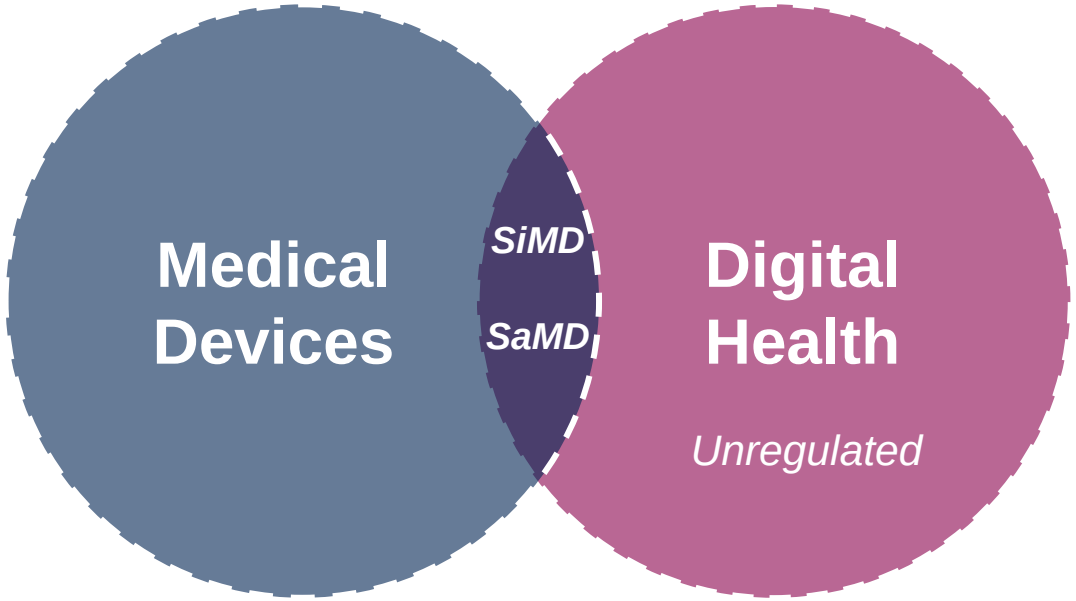
Payment for Digital Products Depends on Type: SaMD or SiMD

Software in a Medical Device (SiMD) are devices with software but regulated and reimbursed like other medical devices. Software as a Medical Device (SaMD) includes a wide range of software products and several commercial models.

Medical devices with embedded software (SiMD) are typically covered under the medical benefit:

- Current Procedural Terminology (CPT)
- Healthcare Common Procedure Coding System (HCPCS)
- Diagnosis-Related Group (DRG)
- Ambulatory Payment Classification (APC)



Payment for SaMD products is highly variable:

- Provider expense or capex
- Patient self-pay
- Payer programmatic spend
- Value-added services
- Claims-based reimbursement

Any digital strategy needs to assess how products are regulated, whether claims-based reimbursement is possible, and who will pay.

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SaMD Market Access Challenges CLAIMS BASED

CMS does not recognize a "benefit category" for SaMD products. According to AdvaMed, CMS can place SaMD and SiMD in existing benefit categories. Congress has proposed legislation to create a benefit category for DTx



Coding

Can our device or procedure be billed under an existing code, or can we obtain a new code?

- Medical devices with embedded software (SiMD) may bill under existing codes.
- Some SaMD with negotiated payer contracts bill under miscellaneous codes.
- **Few SaMD-specific codes (e.g., radiology) exist.**



Coverage

Will payers cover our device or procedure?

- HEOR data is needed for both SaMD and SiMD.
- **Benefit category is not defined for SaMD.**



Reimbursement

What level of reimbursement will we achieve?

- Reimbursement "for actionable review by the healthcare provider (HCP)" may be easier than for reimbursement for an actual SaMD product.

SaMD companies today have had challenges in all three elements of obtaining market access.

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Programmatic Spend vs. Claims-Based Reimbursement

Programmatic Spend

- Negotiated payer-by-payer
  - Stakeholders who make decisions are not the same committees as those who review traditional coverage (i.e., claims-based reimbursement)
- Most common with employer-sponsored plans
- Price set in negotiation
  - Typically covers population per member per month (PMPM)
  - Whole membership or targeted segments
- Rebates and discounts often negotiated based on prospective real-world evidence
  - For example, demonstrating reduction in healthcare utilization over a year
  - At end of year, manufacturer would rebate to payer pre-determined amount if contractual outcomes metrics are not achieved

Claims-based Reimbursement

- New DTx are reviewed by Medical Technology, P&T, or Digital Formulary Committees who consider
  - FDA submission data
  - FDA clearance is generally a prerequisite but will not guarantee coverage
  - Peer-reviewed clinical data
  - HEOR data to show cost offsets or cost savings
- Payer sets reimbursement payment level (which may be much less than manufacturer price)
- Negotiations are common but not required to achieve this coverage

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Medical Benefit Coding Requirements: Coding Sets

Two code types are used to track and bill for outpatient medical procedure use: CPT codes and HCPCS codes. A standardized coding process was mandated under HIPAA Title II, passed in 1996.

American Medical Association

Current Procedural Terminology (CPT) Codes

- **CPT codes offer providers and payers a uniform language for coding medical services and procedures** to streamline reporting, increase accuracy and efficiency, and process claims.
- CPT codes are the **most widely accepted medical nomenclature** used across the country for both public and private markets.

Center for Medicare & Medicaid Services

Healthcare Common Procedure Coding System (HCPCS) Codes

- **HCPCS codes offer providers and payers a uniform language for coding medical services, procedures, and non-physician services** for Medicare and Medicaid.
- Note that HCPCS Level I codes are CPT codes.

Note that while SaMD as medical devices would not automatically be reviewed through this process, some medical devices (e.g., Abbott Libre) have negotiated coverage on pharmacy benefit in return for substantial price discounts.

HIPAA: Health Insurance Portability and Accountability Act, Source: www.ama-assn.org; www.CMS.gov, Note: All inpatient treatment is billed under DRG codes.

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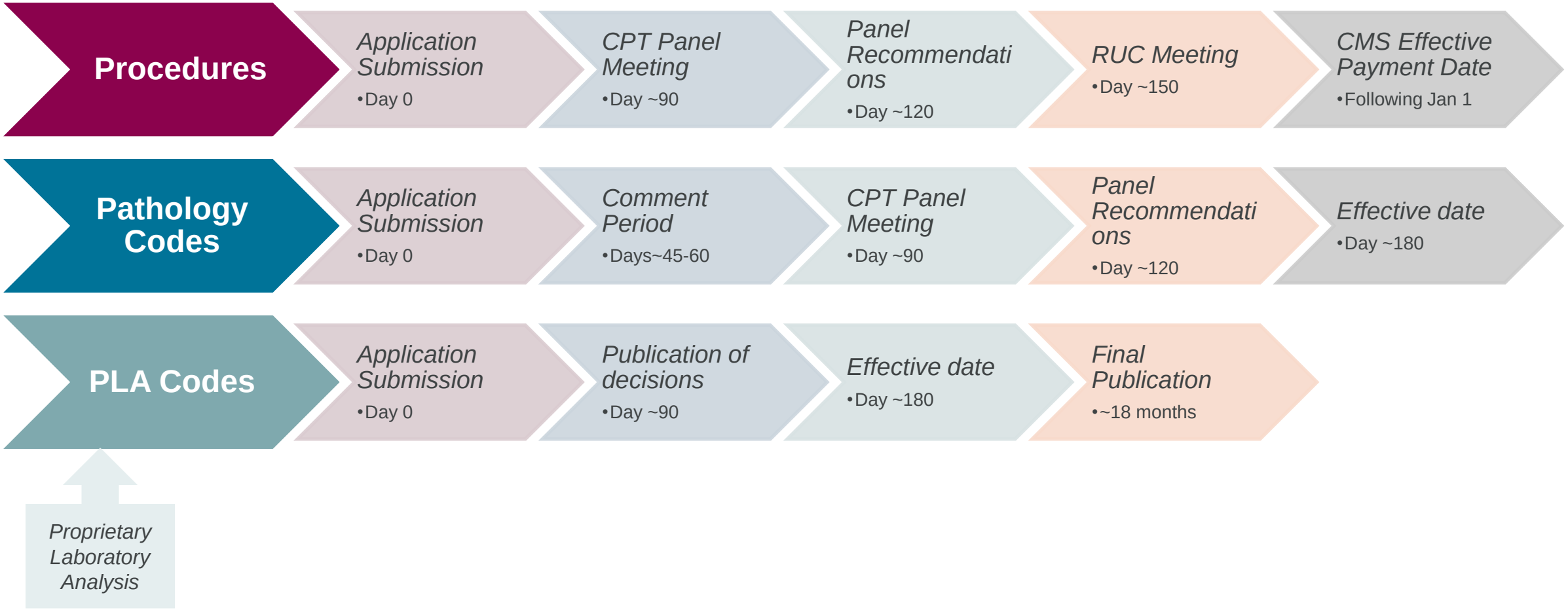
CPT coding process

While the application review process is at least 120 days, pathology (including PLA) codes can become effective in less time than other procedures



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Payer Benefit Categories for Commercial Insurance

- **Determined by payer NOT manufacturer—US market is heterogenous in 2021**
- **Manufacturer should focus on how much patient will have to pay out of pocket rather than benefit class**



Pharmacy Benefit

Reimbursement and management of FDA-approved pharmaceuticals (i.e., regulated by the FDA as a drug)

- Examples: Forxiga, Invokana, Lipitor

Rare exceptions are negotiated payer by payer

- Examples: Abbott Libre flash glucose monitor, Pear Therapeutics

Out-of-Pocket Cost:
- Determined by Formulary Placement, can be negotiated (usually for lower reimbursement level)
- Ranges from $10 to 20% coinsurance



Medical Benefit

Reimbursement and management of medical procedures conducted by HCPs, medical devices, and durable medical equipment (DME)

- Examples: cognitive behavioral therapy, physician office visits, blood glucose monitors, CPAP devices, home oxygen equipment

Because DTx is regulated as SaMD (Software as a Medical Device), most payers presume placement on medical benefit

Out-of-Pocket Cost:
- Determined by coverage decision, can be negotiated
- For devices: post-deductible and 20% coinsurance
- For services: $50-$100 copay or 20% coinsurance

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Coding Requirements Differ by Benefit Placement

Coding requirements for products vary by benefit type, with medical benefit placement requiring an HCPCS (including Level II aka CPT) code and pharmacy benefit placement requiring an NDC-like code, which is the listing number for a compendia.



Pharmacy Benefit

NDC-Like Code (UDI/NHRIC)

- **Payers and PBMs who are open to pharmacy benefit placement require an NDC-like code and compendia listing** for a product to be placed on the pharmacy benefit.
- **An NDC-like code is required** for a product to be processed through payers' existing pharmacy benefit system.
- Codes are tools to facilitate billing, not coverage.
- Existence of a code does not guarantee coverage.
- Once a code is issued, each payer must review and determine (a) if they will cover the product (if it has not been decided earlier), and (b) at what level they will reimburse.



Medical Benefit

HCPCS or CPT Code

- Payers do not feel the product could be billed under existing CBT codes, because those codes specify administration by medical professional.
- **CMS or AMA regulate and grant HCPCS or CPT codes, respectively**.
- **Miscellaneous HCPCS and CPT codes are commonly used for novel products** that cannot be billed under an existing code until a unique code is issued by CMS or AMA. However, each claim is manually adjudicated, and payment, if any, ~~is~~ may not be consistent. Notably, payment levels under miscellaneous codes are typically used by payers when setting reimbursement rates for newly issued codes.

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Medical Benefit Reimbursement Process: Payer Coverage Decisions

Procedures and medical devices are evaluated by the medical technology committee, but medical devices and procedures are less frequently reimbursed compared to pharmaceutical products. Reimbursement amounts are also independently set by the payer, with substantially less manufacturer influence.

Fixed

Inputs

Clinical Data
(Efficacy and safety, FDA label, peer reviewed literature)

Indication Unmet Need

Physicians' Opinion

NOTE: *Medical device manufacturers have less influence on the reimbursement of a product compared to pharmaceuticals*

Medical Technology Committee Review



Meet every 3-6 months to review procedures for coverage.

Voting members include medical directors.

Decisions are made based on a procedure or medical device's fixed inputs and cost and are **heavily influenced by CMS coverage decisions.**

Output

Coverage Decision
Coverage vs. non-coverage (investigational)

Utilization Restrictions
Prior authorization requirements

Reimbursement Level
Payment level often set as a percentage of Medicare

Patient Cost Sharing
*Usually 20% of costs after deductible is met**

Timeline: >1 year

*Subject to maximum out-of-pocket limits for patients

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QUESTIONS?

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THANK YOU

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