Digital Therapeutics: Voice of the Payer

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Precision For Value

Agenda

- Insurance fundamentals

- Where does Digital Therapeutics fit?

- Remember this!

Insurance fundamentals

United States: Insurance and Risk

Self-Insured

The *employer* holds the risk and pays for all medical and pharmacy claims as they are incurred.

Fully-Insured

The *insurance carrier* holds the risk of additional expenses above the premiums collected

Insurance

Pharmacy Benefit

- Pays for claims submitted by a pharmacy within the network
- ~20% of all claims submitted

Medical Benefit

- Pays for claims submitted by a healthcare provider (HCP) within the network.
- ~80% of claims submitted

Medical Necessity

- Medical Necessity means health care services that a physician, exercising prudent clinical judgment, would provide to a patient.

- Generally accepted standards of medical practice means the standards that are based on credible scientific evidence published in peer-reviewed, medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations, the views of physicians practicing in the relevant clinical area and any other relevant factors

Fully-Insured

- A certificate of coverage(COC) or Evidence of Coverage (EOC) is an official contract that outlines what an insured is entitled to, and what they aren't insured for, under a health insurance policy

Self-Insured

- The summary plan description (SPD) is an important document that tells participants what the plan provides and how it operates. Summary of Benefits and Coverage (SBC) describes the benefits and coverage under the applicable plan.
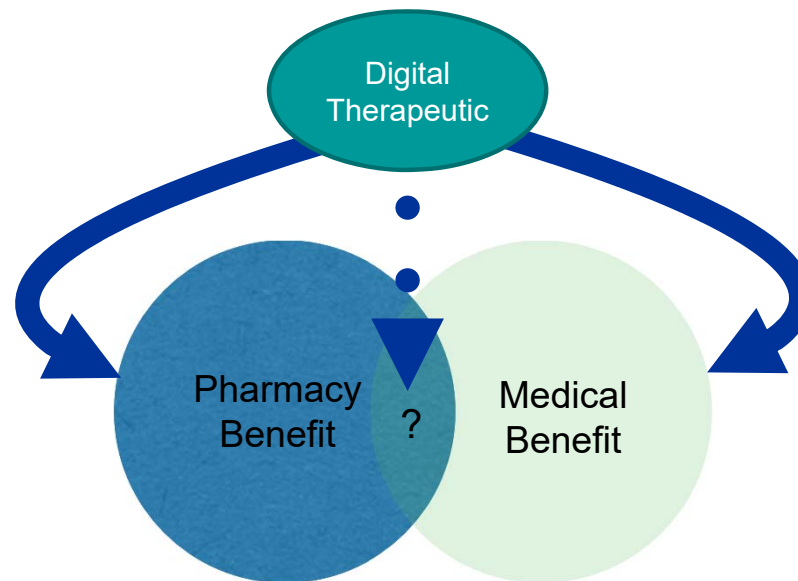
Path to Coverage

Reimbursement is driven by product classification & their codes

Pharmacy

Typically a product with approval from the Food and Drug Administration (FDA)

- National Drug Code (NDC) is a eleven digit numeric code and is obtained/maintained by the FDA
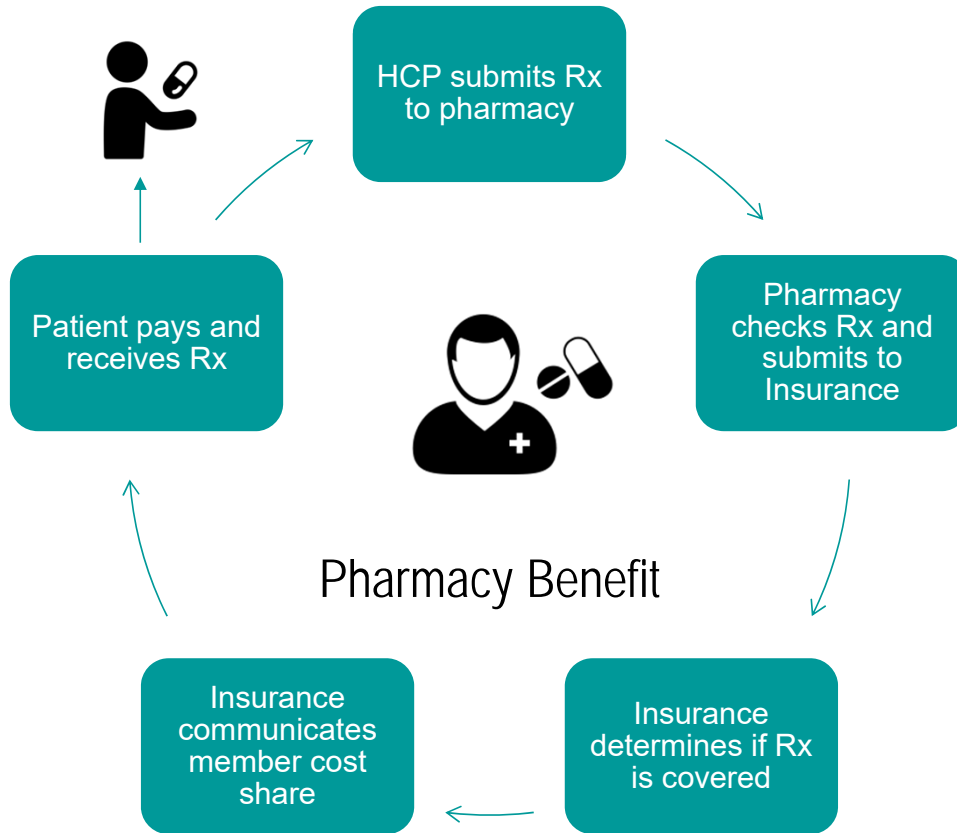

Medical

Typically a product with a 510K approval and falls under two sets of codes:

- Healthcare Common Procedure Coding System (HCPCS) begins with an alpha and are five alphanumeric characters long. Identifies products, supplies, and services and is maintained by the Centers for Medicare & Medicaid Services (CMS)
- Current Procedural Terminology (CPT) code begins with a numeric and are five characters long, and may be numeric or alphanumeric. Describes medical, surgical, diagnostic, and other types of services. The American Medical Association (AMA) holds the copyright to CPT.

Pharmacy Claims

HCP submits Rx to pharmacy

Pharmacy checks Rx and submits to Insurance

Patient pays and receives Rx

Pharmacy Benefit

Insurance communicates member cost share

Insurance determines if Rx is covered

- Prescriptions are often subject to medical necessity review (formulary, prior authorization, step therapy, etc.)

- Reimbursement is based on Pharmacy network contract and/or manufacturer contract

- Claims are real time

Rx = prescription
HCP = Healthcare Provider
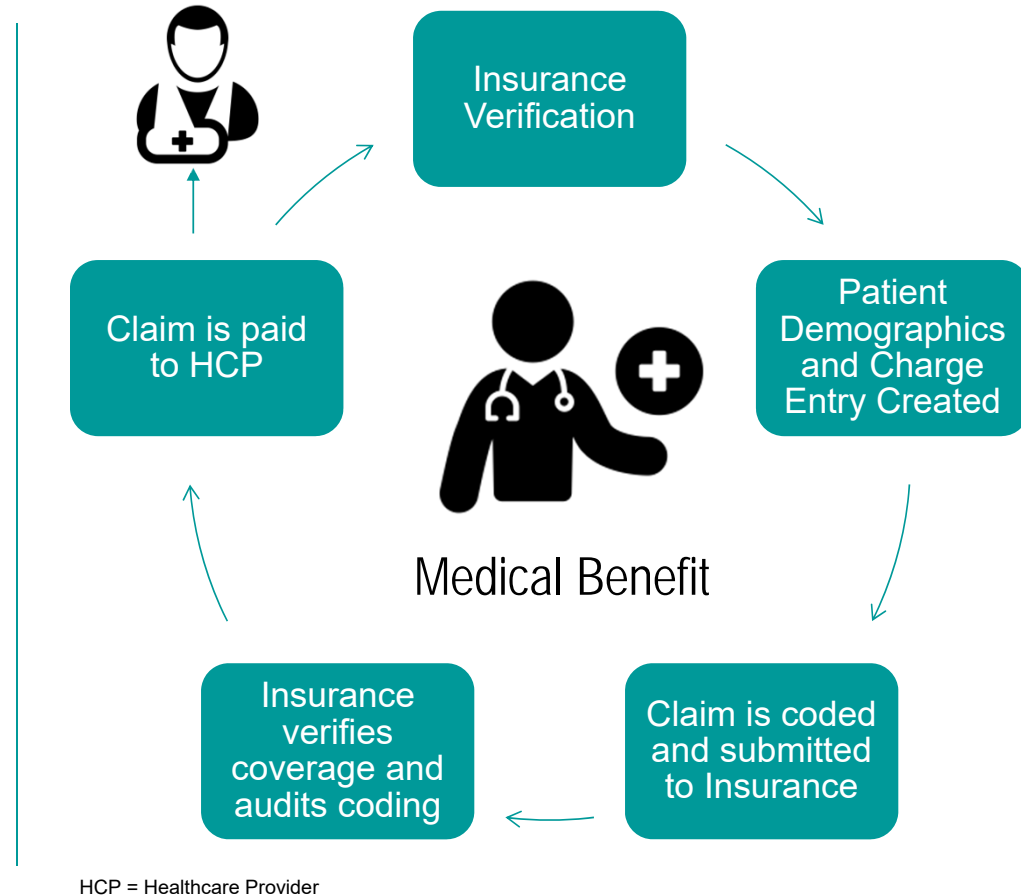
Digital Therapeutics/Health Formulary

- A formulary is a list of prescription drugs covered by a health insurer
- In 2020, Express Scripts will introduce a digital health formulary, which they define as a curated list of technology and software enabled applications and devices that help patients prevent, manage or treat a medical condition
- Digital Health formulary review process:
    - A comprehensive process overseen by physicians, pharmacists and experts in health research and user experience
    - The review will include: clinical outcomes, therapeutic value, effective usability, and stringent security and privacy standards, followed by cost effectiveness
    - Initial focus will include solutions for diabetes, cardiovascular, behavioral health and pulmonary conditions, and will later expand to include tools for other chronic and complex conditions

Express Scripts is pharmacy benefits manager and was recently acquired by Cigna; they have 100 million members and process 1.4 billion prescriptions annually

Medical Claims

- Services are often subject to medical necessity review (pre-certification)

- Claims are audited for proper coding often resulting in modifications

- Claims can lag for >90 days

- Reimbursement is driven by network contractual terms with the provider and/or facility

Insurance Verification

Patient Demographics and Charge Entry Created

Claim is paid to HCP

Medical Benefit

Claim is coded and submitted to Insurance

Insurance verifies coverage and audits coding

HCP = Healthcare Provider

Where does Digital Therapeutics fit?

Similarities & Differences Across Therapies

Similarities

Factor	Traditional Therapeutic	Digital Therapeutic
Access	Prescription Required	Prescription Required

Differences

Factor	Physical Therapeutic	Digital Therapeutic
Forms	Varies from small molecules to biologics	Via a mobile application
Delivery	Various routes of administration	Via a mobile or IoT device
Monitoring	Only a scheduled appointments	HCP dashboard
Analytics	Retrospective claims based analysis	Flexible suite with current and retrospective views
Coding	NDC, CPT, HCPCS…	Varies…

Reimbursement Approaches

Direct Contract (PMPM)

- A PMPM contract pays a vendor a flat fee per member per month
- Metabolic Syndrome Coaching App

Assume 1 million member insurance plan paying $0.02 PMPM

$0.02 * 1,000,000 * 12

$240,000 / year

Pharmacy Benefit (Claims)

- A claim is submitted from a network pharmacy with a valid NDC and is paid off a predetermined fee schedule
- Diabetes management app

Assume 1 million member insurance plan paying $200 per Rx per month

$200 * 100 Rx * 12

$240,000 / year

Value Based Contract (VBC)

- Vendor received reimbursement based on contractually defined goals (metrics)
- Inhaler sensors used to track adherence

Assume 1 million member insurance plan paying $2000 for 80% adherence

$2000 * 120 members

$240,000 / year

Remember this!

Key Points of Information

United States insurance payers are constantly balancing risk (costs) with what services they cover

Reimbursement for digital therapies are inconsistent and vary from payer to payer

Coverage along with management is coming with the introduction of a digital health formulary in 2020

Thank you…