The 3Ps of Digital Endpoint Value

PATIENTS · PHARMA · PAYERS

Key Terms Glossary

Claim | A request for reimbursement of healthcare service and drug costs sent by either a patient or a distributor to an insurance company. (Source: Investopedia)

Co-pay | A fixed amount paid by the patient, on top of their deductible, for a covered health care service. (Source: Healthcare.gov)

Deductible | The amount a patient pays for covered health care services before their insurance plan starts to pay. (Source: Healthcare.gov)

Digital Clinical Measures | Health outcomes or physiological characteristics of an individual's health, wellness, and/or condition that are collected digitally with a sensor. (Source: The Playbook)

Distributors | Wholesale drug retailers and pharmacies. (Source: Business.com)

Endpoint | A precisely defined variable intended to reflect an outcome of interest that is statistically analyzed to address a particular research question. (Source: BEST Glossary)

Formulary | A list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits. Also called a drug list. (Source: Healthcare.gov)

Gemeinsamer Bundesausschuss (G-BA) | The Federal Joint Committee (G-BA) is a public legal entity comprising the four leading umbrella organizations of the self-governing German healthcare system: the National Associations of Statutory Health Insurance Physicians and Dentists, the German Hospital Federation, and the Central Federal Association of Health Insurance Funds. (Source: G-BA)

Integrated Evidence Plan (IEP) | Processes and documents which outline a strategy to connect labeling concepts (i.e. the claims associated with a new drug) to the evidence-generating trials and studies in the drug program. (Source: McKinsey)

Insurance companies | Companies that contract individual people to pay some or all of their health care costs in exchange for a premium. (Source: Healthcare.gov)

Haute Autorité de Santé (HAS) | An independent public authority (API) in France tasked to improve the quality of patient care and to guarantee equity within the healthcare system. (Source: HAS)

Health technology assessment (HTA) bodies | Regional and national HTA bodies provide recommendations on medicines and other health technologies that can be financed or reimbursed by the healthcare system in a particular European Union (EU) Member State or region. (Source: EMA)

Health-Related Quality of Life (HRQoL) | An individual's or a group's perceived physical and mental health over time. (Source: CDC)

HHS | The US Department for Health and Human Services. (Source: HHS)

Krankenkassen (Sickness Funds) | Heavily regulated, non-profit insurers who are legally required to accept all applicants and are permitted to sell health insurance (Source: AICGS)

List price | The price a drug manufacturer initially sets for a given drug. (Source: DrugCost Facts)

Medicare | The federal health insurance program for people who are 65 or older, certain younger people with disabilities, and people with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a transplant, sometimes called ESRD). The different parts of Medicare help cover specific services: Medicare Part A (Hospital Insurance) covers inpatient hospital stays, care in a skilled nursing facility, hospice care, and some home health care; Medicare Part B (Medical Insurance) covers certain doctors' services, outpatient care, medical supplies, and preventive services; Medicare Part D (prescription drug coverage) helps cover the cost of prescription drugs (including many recommended shots or vaccines). (Source: Medicare.gov)

Minimal clinically important difference (MCID) | The smallest change in an outcome that a patient would perceive as clinically meaningful. (Source: Practical management of Pain)

National Institute for Health and Care Excellence (NICE) | An executive non-departmental public body of the Department of Health and Social Care in England whose role is to improve outcomes for people using the NHS and other public health and social care services (Source: NICE)

Patient reported outcome (PRO) | A measurement based on a report that comes directly from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. (Source: BEST Glossary)

Pharmaceutical (Pharma) company | A commercial business licensed to research, develop, market and/or distribute drugs, most commonly in the context of healthcare. (Source: Science Daily)

Pharmacy Benefit Managers (PBMs) | Intermediaries in the process by which the price paid for a drug is determined. Work for insurance companies, large employers and government agencies. (Source: Time)

Prescription drugs | A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease that is: Prescribed by a doctor; Bought at a pharmacy; Prescribed for and intended to be used by one person; and Regulated by FDA through the New Drug Application (NDA) process. (Source: FDA)

Quality-adjusted life year (QALY) | A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health. QALYs are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality-of-life score (on a 0 to 1 scale). It is often measured in terms of the person's ability to carry out the activities of daily life, and freedom from pain and mental disturbance. (Source: Nice.org)

Real World Data (RWD) | Data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. RWD can come from a number of sources. (Source: FDA)

Real World Evidence (RWE) | The clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD. RWE can be generated by different study designs or analyses, including but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective). (Source: FDA)

Service Médical Rendu (SMR) | The benefit set by the French Haute Autorité de Santé (HAS) is a criterion which takes into account several aspects: the seriousness of the pathology for which the medicine is indicated; and the data specific to the drug itself in a given indication (Source: HAS)

Standard of care | A diagnostic and treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance. (Source: Medicine Net)

Supply chain | All the steps that must be taken to ensure medications are available and accessible to patients. A wide range of stakeholders are also involved in the pharmaceutical supply chain, including manufacturers, wholesale distributors, and pharmacy benefit managers (PBM). (Source: Pharma News)

Value based agreements (VBAs) | A written contractual arrangement between parties in which the payment for healthcare goods and services is tied to predetermined, mutually agreed upon terms that are based on clinical circumstances, patient outcomes, and other specified measures of the appropriateness and effectiveness of the services rendered. (Source: Bulletin Facs)