

Term	Definition
Affordability	An assessment of a person's ability and willingness to pay. It is an interaction of spending, income, and judgments about the value of something relative to its price. ¹
Comparative Effectiveness Research (CER)	The generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy-makers to make informed decisions that will improve health care at both the individual and population levels. ²
Cost-Effectiveness Analysis (CEA)	A method to examine both the costs and health outcomes of one or more interventions. It compares an intervention to another intervention (or the status quo) by estimating how much it costs to gain an additional unit of some health outcome, such as a life-year gained or a case prevented.
Co-Insurance	The percentage of costs of a covered health care service you pay (20%, for example) after you've paid your deductible. ³
Co-Payment or Co-Pay	A fixed amount (\$20, for example) you pay for a covered health care service after you've paid your deductible. ⁴
Cost-Sharing	The share of costs covered by your insurance that you pay out of your own pocket. This term generally includes deductibles, co-insurance, and co-payments, or similar charges, but it doesn't include premiums, balance billing amounts for non-network providers, or the cost of non-covered services. Cost-sharing in Medicaid and CHIP also includes premiums. ⁵
Deductible	The amount you pay for covered health care services before your insurance plan starts to pay. With a \$2,000 deductible, for example, you pay the first \$2,000 of covered services yourself. ⁶
Economic Burden	In medicine, a term used to describe problems a patient has related to the cost of medical care. Not having health insurance or having a lot of costs for medical care not covered by health insurance can cause financial problems and may lead to debt and bankruptcy. Economic burden can also affect a patient's quality of life and access to medical care. For example, a patient may not take a prescription medication or may avoid going to the doctor to save money. Cancer patients are more likely to have economic burden than people without cancer. Also called economic hardship, financial burden, financial distress, financial hardship, financial stress, and financial toxicity. ⁷
Financial Burden	Healthcare financial burden is defined as the proportion of total OOP medical expenditures divided by total income for each family. ⁸
Health Economic Modeling	A set of analytic approaches in health economic analysis that synthesize clinical, epidemiological, and economic evidence from different data sources into an evaluation framework that will enable researchers or decision-makers to generate estimates for specific outcomes of interest. Models are usually a simplified representation of the real world to inform decision-making by characterizing uncertainty in projecting outcomes. ⁹
Health Technology Assessment (HTA)	A multi-disciplinary process that uses explicit methods to determine the value of a health technology at different points in its life cycle. A health technology is the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of lives for individuals affected. ¹⁰

1 University States of Care (2018). University of Pennsylvania LDI of Economics. https://ldi.upenn.edu/wp-content/uploads/archive/pdf/Penn%20LDI%20and%20USofC%20Affordability%20Issue%20Brief_Final.pdf

2 Sox HC. Defining comparative effectiveness research: the importance of getting it right. *Med Care*. 2010 Jun;48(6 Suppl):S7-8. doi: 10.1097/MLR.0b013e3181da3709. PMID: 2073202.

3 <https://www.healthcare.gov/glossary/co-insurance/>

4 <https://www.healthcare.gov/glossary/co-payment/>

5 <https://www.healthcare.gov/glossary/cost-sharing/>

6 <https://www.healthcare.gov/glossary/deductible/>

7 National Institute for Health, National Cancer Institute.

8 Kielb ES, Rhyon CN, Lee JA. Comparing Healthcare Financial Burden With an Alternative Measure of Unaffordability. *Inquiry*. 2017 Jan 1;54:46958017732960. doi: 10.1177/0046958017732960. PMID: 28975850; PMCID: PMC5798734.

9 Glossary – Health Economics [online]. (2016). York; York Health Economics Consortium; 2016. <https://yhec.co.uk/glossary/>

10 O'Rourke, Brian, Wija Oortwijn, and Tara Schuller. "Announcing the New Definition of Health Technology Assessment." *Value in Health* 23.6 (2020): 824-825.

Term	Definition
Patient-Centered Value Assessment	Value assessment that reflects the diversity of patient preferences and circumstances, includes patients as equal partners throughout the development process, incorporates methods to address health equity, and reflects real-world patient and caregiver experiences.
Patient-Centered Outcomes	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. ¹¹
Patient-Centered Core Impact Set	A "patient-derived and patient-prioritized list of impacts a disease and/or its treatments have on a patient (and/or their family and caregivers). Intentionally broad and inclusive, the term 'impacts' includes short-term and long-term health outcomes and any other related implications (e.g., career/family stresses, economic burden, career loss)." ¹²
Patient Engagement	"The active, meaningful, and collaborative interaction between patients and researchers across all stages of the research process, where research decision-making is guided by patients' contributions as partners, recognizing their specific experiences, values, an expertise." ¹³
Patient Inputs	A wide range of information and perspectives from patients including, but not limited to, informal comments; patient opinions expressed publicly, including social media; patient responses to qualitative surveys; and quantitative measurements of patient-reported outcomes.
Patient Perspective	A specific type of patient input describing patients' experiences with a disease or condition and its management.
Patient Preference	Qualitative or quantitative assessment of the relative desirability or acceptability to patients of specified alternatives or choices among outcomes or other attributes that differ among alternative health interventions. ¹⁴
Premium	The amount you pay for your health insurance every month. In addition to your premium, you usually must pay other costs for your healthcare, including a deductible, co-payments, and co-insurance. If you have an ACA Marketplace health plan, you may be able to lower your costs with a premium tax credit. ¹⁵
Real-World Data (RWD)	Real-world data are the data relating to patient health status and/or the delivery of healthcare routinely collected from a variety of sources. RWD can include: <ul style="list-style-type: none"> • Electronic health records (EHRs) • Claims and billing activities • Product and disease registries • Patient-generated data including in-home-use settings • Data gathered from other sources that can inform on health status, such as mobile devices.¹⁶
Real-World Evidence (RWE)	Real-world evidence is the clinical evidence regarding the usage and potential benefits of 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, and observational studies (prospective and/or retrospective). ¹⁷
Social Determinants (or Drivers) of Health	Social determinants (or drivers) of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. ¹⁸
Value Element	Refers to specific aspects or components that stakeholders may consider to be part of an overall assessment of value (e.g., different mode of administration, reduced risk, lower cost).
Value Assessment (VA)	Comparison of the relative benefits of the costs of a given technology or service for a specific person or population.

11 National Quality Forum

12 Peretto, E.M., Oehrlein, E.M., Love, T.R. et al. Patient-Centered Core Impact Sets: What They Are and Why We Need Them. *Patient* (2022). <https://doi.org/10.1007/s40271-022-00583-x>

13 <https://www.sciencedirect.com/science/article/pii/S1098301520301418>

14 ISPOR-FDA Summit 2020: Using Patient-Preference Information in Medical Device Regulatory Decisions: Benefit-Risk and Beyond [internet]. Available from: <https://www.ispor.org/conferences-education/conferences/past-conferences/ispor-fda-summit-2020>

15 <https://healthcare.gov/glossary/premium/>

16 <https://fda.gov/science-research/science-and-research-special-topics/real-world-evidence>

17 <https://fda.gov/science-research/science-and-research-special-topics/real-world-evidence>

18 Healthy People 2030, U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. <https://health.gov/healthypeople/objectives-and-data/social-determinants-health>