

Principles for Value Assessment in the U.S.

Value assessment is an important process to inform national and local deliberations about allocating resources and achieving the best clinical health and quality-of-life outcomes. As exploration of a systematic, centralized process for review of drugs and other health interventions in the U.S. accelerates, the Innovation and Value Initiative (IVI) believes there is a need to define the principles that must guide future policy and practice.

An overarching theme of these principles is defining best practice in the applied use of value assessment; there must be consensus among stakeholder communities on the most effective methods and use cases that are relevant to the U.S. marketplace.

Sustains Authentic Patient-Centricity

Value assessment must consistently establish diverse patient partnerships in governance, priority setting, and the creation of models.

Assessors should lead robust research in patient preference and data improvement to ensure value assessment is authentic and relevant to the diverse patient experience.

Cultivates Modernized Methods

Value assessment initiatives must support the evolution of traditional cost-effectiveness analyses and complementary approaches that address societal perspectives and broader cost parameters, as well as reduce discrimination and disparities based on patient heterogeneity or disability.

Improves Clinical and Real-World Data

Value assessment must define priorities for data resource investments, including patient-provided information. The standardization of real-world data generation and the practical implication of data sources in value assessment must also be prioritized.

Adapts To and With Evolving Evidence

Value assessment must contribute to a continuous learning environment. Model developers can do this by accounting for scientific uncertainty, patient heterogeneity, and evolving evidence related to disease states and clinical outcomes, quality-of-life impacts, and disparities in care.

Fosters Long-Run Innovation

Value assessment must be able to recognize and distinguish transformative therapies and inform national dialogue about incentivizing and rewarding technological innovation.



Advances Transparency

Value assessment in the U.S. should accelerate the development of open-source modeling and application to improve stakeholder trust and establish open dialogue. Assumptions and coding should be transparent to allow public validation and stimulate replication across disease and interventional analyses.

Focuses Value Discussion Across Treatment Interventions

Value assessment must evolve beyond siloed comparisons within a class or intervention type to consider benefit, risk, and trade-offs for optimal treatment approaches.

Facilitates Customizable Decision-Making

Decision-maker needs should inform the development of value assessment methods and tools. In turn, such resources should include customizable analyses and tools to support localized decisions.

Supports Health Equity

Value assessment should facilitate subgroup and distributional impact analyses; drive improved methods in clinical, outcomes, and preferences research to reflect diverse communities and experiences; and inform policy dialogue about improving access and equity.