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UCB Principles for Value Assessment in the U.S.

The United States' healthcare system is evolving from volume-based approaches toward value-based approaches and, with that shift, frameworks for capturing, measuring and assessing value are becoming increasingly important. UCB recognizes the importance of value-assessment frameworks within the U.S. healthcare system but feels strongly that, in order to offer value, those tools derived from value-assessment frameworks must adhere to certain broad principles of operation and support sustainable value and equitable access to healthcare.

1. Value-assessment tools must be patient-centered.

- Value-assessment tools must incorporate patient perspectives, account for impact on wholistic patient experiences and should reflect not only population-level information, but also individual patient viewpoints and disease journeys.
- Value-assessment tools must consider the direct and indirect benefits of a treatment, particularly those most important to the patient. For example, progression of disease, symptom control, a treatment's impact on productivity, ability of a patient to participate in activities of daily living, impact on caregiver burden, improvement over alternative treatments, impact on public health, and the value of hope.

2. Value-assessment frameworks must be transparent and adaptive to differing circumstances (e.g., orphan drugs).

- Value-assessment frameworks and its tools, methods, coding, criteria, and assumptions should be transparent to all stakeholders and allow for meaningful stakeholder comment.
- Value-assessment organizations should make their methodology, evidence model, data, and data sources publicly available and provide sufficient detail in their protocols to clarify areas that are open to interpretation and impacted by assessment assumptions.
- Value assessment reports should clearly articulate the decision context and how the value assessment framework is meant to be used.
- The approach to value assessment needs to be dynamic. Depending on the disease state, how it impacts patient lives, and how technology advances, value assessments need to evolve with advancements in healthcare and also consider delayed progression disease and disability when possible. Value assessments should be revisited on a regular basis and/or when circumstances change (e.g., new evidence, new indication, etc.).

3. Value assessments must focus on all aspects and perspectives of healthcare.

- Value assessments should focus broadly on all aspects of the healthcare system, rather than a sole payer perspective.
- For example, focusing only on costs associated with prescription drugs and not considering other important components of the healthcare system (e.g., procedures, diagnostic tests, hospitalizations, office visits) or indirect benefits to the patient or society will provide an incomplete perspective on value.

4. Value-assessment frameworks must be validated, be able to be replicated, subject to peer-review, utilize rigorous methodologies in a timely manner, include multiple stakeholders throughout its development, and revise as necessary (e.g., when new standards, methods, clinical data, etc. become available).

- Value-assessment frameworks should undergo rigorous testing throughout development and be regularly reviewed to ensure that they are using well-established standards, as well as, up to date methodologies, and keeping up with new medical data and innovations.
- Value-assessment tools should be reproducible and subject to peer-review. Testing, validation and review should include meaningful input from multiple stakeholders, including patients, providers, policymakers, and manufacturers, in developing and refining the framework.

5. Value-assessment tools must utilize a broad range of high-quality evidence and aim to incorporate digital transformation to enhance its applicability in decision-making.

- Value-assessment tools are only as good as the evidence considered and must incorporate the best available evidence. This not only includes randomized clinical trial data but also, when available, real-world evidence generated from observational studies or other credible data sources, such as patient registries, ultimately demonstrating a more comprehensive picture of a treatment's value to patients, subsets of patients, caregivers, society, etc.
- Value assessments should also consider and, when possible, incorporate the use of innovative digital tools and predictive analytics platforms that can acquire, enhance, and analyze evidence.

6. No single value-assessment framework should be the final arbiter of value within the United States.

- There are several value-assessment tools in use within the United States, and each has its own set of strengths and weaknesses.
- Stakeholders, including payers, must utilize multiple frameworks to support informed decision-making and assess value multilaterally and in a systemic manner, giving more attention to value from the patient and societal perspective, rather than a solely budgetary perspective. Value-assessment entities must endeavor to advance value-assessment methodologies to better account for innovation and evolving patient perspective.

7. Value-assessment methods and processes must better account for populations that are typically underrepresented in research and drivers of health disparities.

- The impact of a treatment on health outcomes and cost differs among patients due to several factors, including those relating to broader drivers of health disparities.
- Value assessment can only serve as an effective tool to support decisions about delivery and reimbursement of healthcare that further improves patient-centeredness and health equity if the frameworks adequately address health disparities and diverse representation of populations.

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