EVIDENCE-INFORMED BENEFITS DESIGN

in the Context of Universal Health Coverage

Proposed Policy Principles
Evidence-Informed Benefits Design in the Context of Universal Health Coverage

Achieving the goals of universal health coverage (UHC) in low- and middle-income countries requires a structured, collaborative effort that ensures health systems use resources effectively and efficiently. Governments, payers, and clinicians need to consider a range of decision-making tools to prioritize health care interventions and ensure patients have access to quality health care products and services to prevent, diagnose, and treat diseases. While there are many evidence-informed decision-making tools available, some governments and payers use health technology assessment (HTA) to help inform health policy decisions.

The most conventional form of HTA is “micro-level” HTA, which focuses on the assessment of individual health technologies such as drugs and medical devices. However, “micro-level” HTA of individual technologies is unlikely to address the systemic challenges faced by healthcare systems in low- and middle-income countries. In contrast, “macro-level” HTA specifically addresses patient access to high quality medical care by assessing the effectiveness and efficiency of interventions within the whole health system and informing the prioritization of health care services. Evidence-informed benefits design uses “macro-level” HTA to inform payers’ decisions on what products and services to cover in benefits packages as countries progress towards UHC and expand beyond basic benefits packages toward comprehensive coverage.

The innovative biopharmaceutical industry believes evidence-informed benefits design that is patient-centered and takes into account the health care delivery system as a whole can help promote long-term sustainability and flexibility in meeting UHC objectives while ensuring that priority setting reflects social values and preferences for investment in health care. Further to its existing proposed public policy principles on UHC, the innovative biopharmaceutical industry proposes the following key guiding public policy principles to inform the design of patient-centered benefits packages.

1. Per the World Bank definition, low- and middle-income countries are classified as economies with GNI per capita of $12,746 or less.

2. Currently, there is no consistent terminology used when discussing the concept of benefits design. In this document, we use the term “evidence-informed benefits design” to refer to the development of benefits packages in low- and middle-income countries. However, other stakeholders use different terminology to discuss the same concept (e.g., the World Bank and World Health Organization use the terms “essential benefits package” and “base benefits package,” while the United Kingdom’s National Health Service prefers “minimum benefits package”).
Benefit design should be patient-centered, evidence-informed, and holistic to effectively and efficiently increase equitable access to quality healthcare services.

• Health system organization and service delivery is complex, requiring decisions on resource prioritization and allocation that ensure equitable access to services, an appropriate set of interventions, and the means to achieve optimal health outcomes. Decisions on health solutions included in a benefits package need to take system wide impacts into consideration, including the range of inputs required to deliver the health care solution or technology (e.g., outpatient or inpatient, level of trained providers, home based follow-up).

• While important, policy decisions on the inclusion of innovative medicines and health technologies in benefits packages represent only one part of the broader discussion around UHC. Governments considering HTA should use broader, “macro-level” approaches to help inform prioritization of interventions across the whole health system.

• Evidence-informed decision-making to support investments in healthcare innovations, including strong health infrastructures, workforce, systems, and social practices, is the foundation for equitable access for all people.

• Through a broader, patient-centered approach, evidence-informed benefits design can reduce health inequalities and promote long-term health system efficiency and sustainability.

Benefit design should be aligned with local context and patient needs.

• There is no one-size-fits-all approach to designing a benefits package. As countries move towards UHC, methods and outcomes will vary from country to country, depending on the organization of a given healthcare system, its objectives and available resources.

• Decisions to expand access to treatments and services should be evidence-informed and consider the social, economic, epidemiological, and cultural environment of the individual low- and middle-income countries.

• In many low- and middle-income countries, lack of health system infrastructure, clinical guidelines, and limited human and financial resources result in insufficient, inefficient and inappropriate use of interventions.

• Governments should tailor benefits design processes to appropriately reflect local contexts to ensure patients have access to timely and appropriate quality care.
3 Transparency

Benefits design should emphasize transparency and stakeholder involvement.

- Key stakeholders – including patients, provider groups, payers, manufacturers, distributors, clinicians, academics, and policymakers – should be actively engaged in the design of a benefits package. This will ensure that investments reflect patient needs, and make it more likely that the results will be widely accepted and implemented by all stakeholders.

- All relevant governmental agencies – health, finance, and beyond – with responsibilities affecting various aspects of health services delivery to different segments of the population should be included in the benefits design process to ensure fair and meaningful access to healthcare services.

- Appropriate mechanisms should be available for stakeholders to provide input into the process from the beginning, clarify assumptions, and provide additional data in response to evaluations. The process should be made clear to the public and policy recommendations should be made available for public comment in a timely manner.

- Broader representation of stakeholder groups will promote the legitimacy and use of evidence-informed benefits design and increase equity within health systems.

4 Access

Benefits design should promote increasing patient access to quality services and care that prevent, slow progression of, or manage diseases.

- The benefits package should increase access to prevention initiatives, quality diagnostics, and quality essential and innovative medicines for both infectious and chronic conditions to improve patient quality of life. If governments are unable to address these areas at the same time, evidence-informed benefits design should help decision-makers prioritize next steps.

- Benefits design should be patient-centered, enabling access to necessary, quality treatments and services, without patients or their families incurring catastrophic financial burdens.

- “Macro-level” HTA can assess how appropriately applied early interventions improve timeliness of screening and diagnosis, reduce progression of chronic conditions, reduce downstream morbidity and mortality, as well as overall health system costs, and achieve significant societal benefits.
**Choice**

Benefits design should inform decision-making and promote choice in health care service delivery for health care providers and patients.

- Designing a benefits package should involve participation from health care providers and patients with direct knowledge or experience of the therapeutic area.
- Benefits design should utilize appropriately developed clinical guidelines to prevent adverse incentives in choice of health services which may result in waste, inappropriate treatment, or undertreatment.
- Patients should be informed and consulted fully to ensure that health systems are providing options that correspond with their needs.
- Benefits design should recognize that individuals respond differently to health interventions and should avoid making decisions solely at the population level. When appropriate, physicians and patients should be able to partner in choosing safe, effective health services that best meet the unique medical needs and values of the individual patient.

**Innovation**

Benefits design should encourage experimentation in health system interventions and promote innovation, including investment in R&D, across the spectrum of prevention, diagnostics, treatment, care, and support.

- Benefits design should be responsive to continuous innovation across the health care spectrum with the underlying goal of improving quality and efficiency of patient care in the health system.
- New and effective interventions should be included in the benefits package and made available to patients as soon as possible through transparent and consultative dialogue with all relevant stakeholders.
- The innovative biopharmaceutical industry can continue to play a role in fostering innovation across the continuum of medical education, prevention, treatment, care, and support in partnership with other stakeholders.
The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry’s 2 million employees research, develop and provide medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

The Japan Pharmaceutical Manufacturers Association (JPMA) is a voluntary association comprising 72 research-oriented pharmaceutical companies. JPMA has been contributing to advancing global healthcare through the development of innovative ethical drugs, facilitating sound development of the pharmaceutical industry through proactively establishing policies and recommendations in response to globalization and enhancing public understanding of pharmaceuticals.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $51.2 billion in 2014 alone.