

## OP09 Investigating The Nature And Scope Of Innovative Payment And Pricing Schemes For Health Technologies

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**Introduction:** Innovative pricing and payment schemes have been proposed to address the affordability issues raised by new health technologies or the uncertainty about their long-term safety and effectiveness. As part of the Horizon Europe project HI-PRIX, we investigated the nature, scope, and impact of these arrangements.

**Methods:** We undertook a PRISMA-ScR-compliant review in PubMed, Web of Science, and Scopus, from 2010 to 2023. We also searched health technology assessment (HTA) agency websites. The search strategy was structured around two blocks: “pricing/payment schemes,” and “innovativeness.” Studies illustrating pricing/payment schemes with sufficient level of details to explain their functioning were selected, also through a nested evaluation of an artificial-intelligence-powered tool for systematic reviews. These schemes were classified according to several criteria, such as their purpose, nature, governance, product category, data collection needs, foreseen distribution of risk, and implementation challenges. The study protocol was published in PROSPERO (CRD42023444824).

**Results:** “Innovative payment and pricing schemes” were defined as arrangements that go beyond price per unit of the technology, simple price/volume agreements, or expenditure caps. Seventy innovative schemes were identified, of which 25 were only illustrated theoretically, while 45 have been implemented in practice. So far, 170 real cases of implementation have been identified. The schemes target pharmaceuticals, vaccines, and/or medical devices. Whether designed to incorporate unique features of a given technology, or to address specific challenges, the schemes can be classified by different value drivers, including type of technology, therapeutic indication, or timeline of the agreement.

**Conclusions:** Available pricing and payment schemes have the potential to offer a comprehensive toolkit to policymakers facing reimbursement and access decisions, highlighting that it is not the scheme per se that is innovative, rather its application/use in a given context or for a given challenge. The catalog populates the Pay for Innovation Observatory, a publicly available repository.

## OP10 Affordability Decision Rules: Systematic Review And Categorization Of Budget Impact Thresholds For 174 Countries Based On International Practices

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**Introduction:** Effective health intervention coverage decision-making hinges on understanding budget impact (BI). Despite progress in estimating cost-effectiveness thresholds, a standardized approach for defining BI, particularly high BI, remains elusive. Addressing this gap, our systematic review aims to identify existing BI thresholds and establish universally applicable BI categories, providing a much-needed framework for global health policy.

**Methods:** In our systematic review, we adhered to Cochrane methods and PRISMA reporting guidelines (PROSPERO protocol CRD42020221652). We included articles that detailed current BI or affordability thresholds used by national or regional healthcare systems, sourcing from PubMed, Embase, and International Network of Agencies for Health Technology Assessment (INAHTA) communications. To address variability across jurisdictions, we normalized BI/affordability thresholds to a fraction of each country's total healthcare expenditure. This approach enabled us to categorize BI thresholds into four distinct levels (low, moderate, high, and very high) and apply these categories universally across countries.

**Results:** We retrieved 1,592 records, identifying affordability thresholds and their underlying rationales in 12 countries: Argentina, Australia, England, Canada, Germany, France, Netherlands, USA, Taiwan, Ukraine, Scotland, and Singapore. Utilizing this data, we established four BI threshold levels relative to the total health budget: low (below 0.00005), moderate (0.00005 to <0.0001), high (0.0001 to <0.0002), and very high ( $\geq 0.0002$ ). We then extrapolated these thresholds, along with their uncertainty ranges, to 174 countries, using 2022 World Bank data.

**Conclusions:** Our study provides a comprehensive overview of current global affordability thresholds and their implications for healthcare coverage and reimbursement. We found that explicit BI thresholds are predominantly established in high-income countries. Our findings offer critical, evidence-based guidance on affordability decision rules, applicable to health systems in 174 countries, thereby contributing significantly to the standardization and informed policymaking in global healthcare.