

UNLOCKING ACCESS

Evaluating the Costs and Benefits of Innovative Pricing and Payment Models in Europe

Background

- Across the EU, policymakers and health stakeholders face the challenge of **sustaining healthcare systems** while **fostering innovation**.
- Financial pressures have driven **cost-containment** and the search for models **enhancing efficiency** and access.
- Innovative Pricing and Payment Models (IPMs) align **affordability, access, and incentives** for high-value innovation, prompting growing stakeholders' interest in their design and implementation.¹⁻⁴
- Evidence shows that **IPMs improve access** where **conventional pricing** models **fall short**, though their complexity and administrative burden remain.⁵⁻⁹

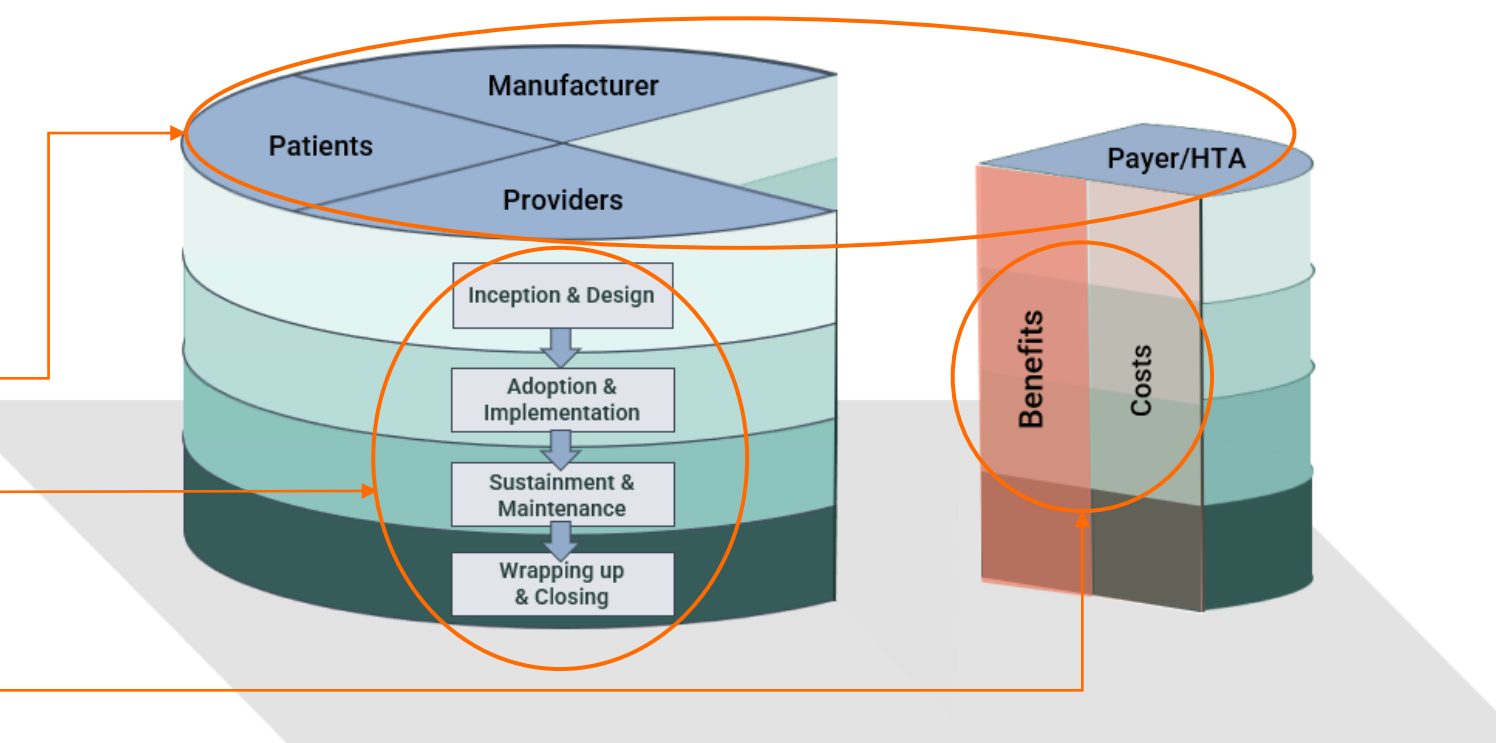
Aims

- To document and assess the tangible and intangible costs and benefits of implementing IPMs across different model types, countries, and stakeholders.
- To apply a structured framework and case studies to capture these costs and benefits comprehensively and inform future IPM implementation.

Methods

Assessment framework:

- Based on implementation science¹⁰⁻¹³
- Four stakeholders
- Four implementation phases
- Stakeholder and phases cross-cutting costs and benefits



FOUR CASE STUDIES BY IPM-TYPE

Outcome-Based Agreement (OBA)

CASE STUDY DESCRIPTION

A patient-level outcomes-based payment model for a gene therapy for haemophilia A in Germany.

Financial-Based Risk Sharing Agreement (FBRSA)

Population-level partially delinked revenue guarantee model for access to antibiotics. Implemented in Sweden.⁷

Portfolio or Bundling Agreement (PoBA)

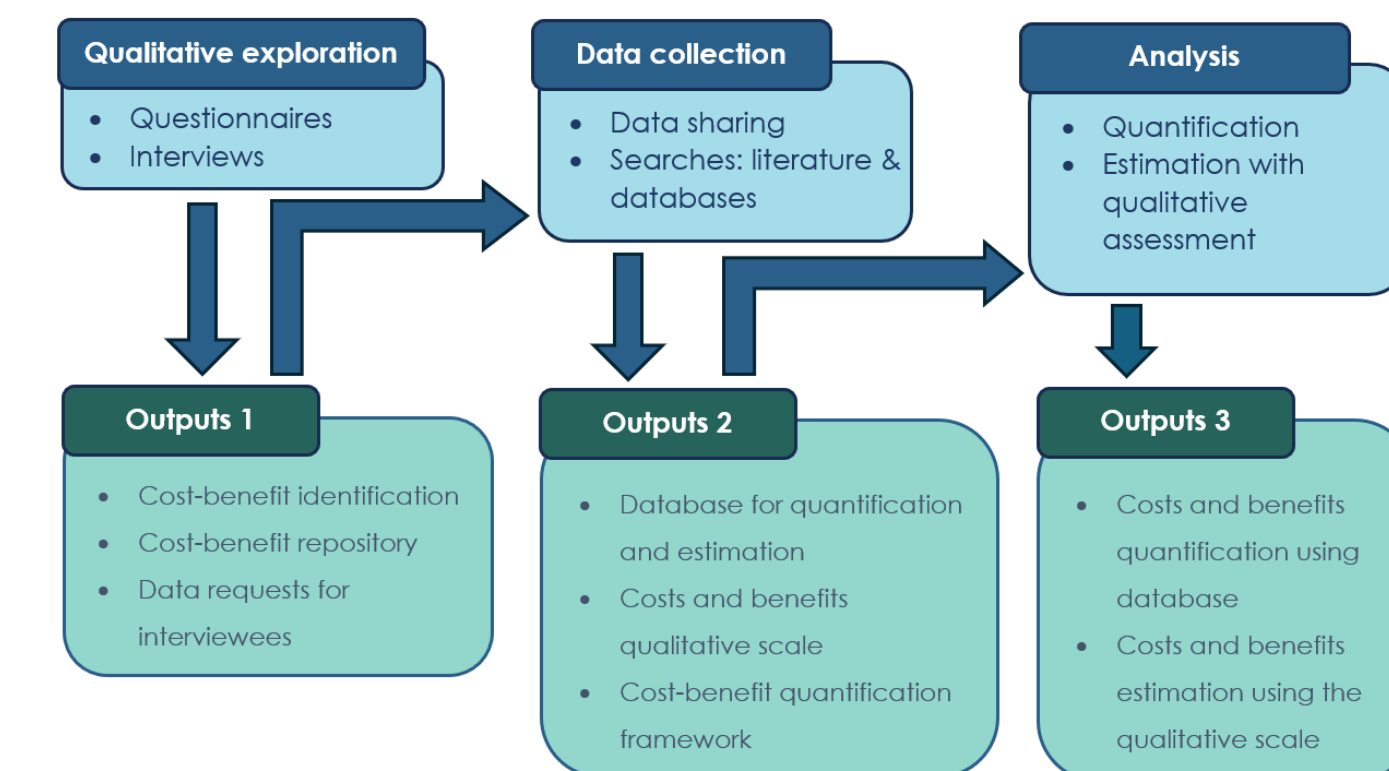
Defined patient population level bundling of two medicines for multiple myeloma in Lithuania.

Instalment and Amortisation Payments (laAP)

A patient-level outcomes-based staged payment model implemented in Italy and Spain to introduce two CAR-T therapies.³

Process for evidence collection and analysis:

- Qualitative exploration: 24 interviews
- Data collection: databases and literature searches
- Analysis: quantifications and qualitative assessments



Results: cost and benefits

1. The cost-benefit inventory

COSTS	PAYERS	MANUFACTURERS	PROVIDERS	PATIENTS	BENEFITS	PAYERS	MANUFACTURERS	PROVIDERS	PATIENTS
Human Resources costs	<ul style="list-style-type: none">NegotiationSet-up of schemeMaintenancePayment processing (e.g. re. IPM risk-sharing nature)Wrap-upOpportunity costs				Health-related benefits	<ul style="list-style-type: none">Efficacy/SafetyQoL		<ul style="list-style-type: none">Efficacy/SafetyQoL	<ul style="list-style-type: none">Efficacy/SafetyQoL
Transaction costs (excluding HR)	<ul style="list-style-type: none">Clinical monitoringInfrastructure for IPM implementationSupply chain, logistics, and storageLegal costsIT costsFinance costs				Revenue		<ul style="list-style-type: none">Anticipated Revenue and return on investment		
Medicine-related costs	<ul style="list-style-type: none">Price	<ul style="list-style-type: none">Adoption		<ul style="list-style-type: none">Out of pocket costs	Cost savings		<ul style="list-style-type: none">Risk-sharing with reduced costs to assetCost-offset	<ul style="list-style-type: none">Cost-offset	
Health-related costs				<ul style="list-style-type: none">Unexpected serious adverse eventsHospitalisationsTravelLack of information and training	Early access	<ul style="list-style-type: none">Early access	<ul style="list-style-type: none">Earlier market launch	<ul style="list-style-type: none">Early access	<ul style="list-style-type: none">Early access
Other costs					Spillovers and other positive externalities	<ul style="list-style-type: none">Knowledge spillover to other schemes or countriesInfrastructure spilloversInnovativeness and preparedness to absorb	<ul style="list-style-type: none">Knowledge spillover to other schemes or countriesInfrastructure spilloverUpstreaming HRInnovation environment e.g. Clinical trialsProvider accreditation	<ul style="list-style-type: none">Scientific spilloverInfrastructure spilloverUpstreaming HRInnovation environment e.g. Clinical trialsProvider accreditation	
					Other benefits	<ul style="list-style-type: none">Political win	<ul style="list-style-type: none">Risk sharing and generation of RWEPredictability of revenue		<ul style="list-style-type: none">Quicker and more optimal adoption

2. Implementation costs and benefits: all case studies combined

Cost & benefits: all case-studies combined	Inception & design				Adoption & implementation				Sustainment & maintenance				Wrap-up & closing			
	Pay	Man	Prov	Pat	Pay	Man	Prov	Pat	Pay	Man	Prov	Pat	Pay	Man	Prov	Pat
Costs	Human Resource cost	2	2-3	1-2		2-3	2	1-2		2-3	2	1-2		1-2	1-2	
	Transaction cost	0-1	2			0-1	2	1-1		0-1	2	1				
	Health-related costs								3			3				3
	Medicine-related cost			1		3		1		3		1		3		1
	Other costs	0-1								0-1		1		0-1		1
Benefits	Health related benefits										3	2			2-3	2-3
	Revenue										2-3			0-1		
	Cost savings										2-3		2	2	1	
	Early access										2	2	1-2	1-2	2	1-2
	Spillovers/ pos. externalities	1	0-1			1-2	1			1-2	1	1-2		1	1	1-2
	Other benefits	0-1	1			0-1	0-1				0-1			1-2	2	

Abbreviations: Pay = Payer/HTA; Man = Manufacturer; Prov = Provider; Pat = Patient / Scores: 3= Significant; 2= Moderate; 1= Minor

Costs:

- ✓ Significant HR and transaction costs for payers/HTA, manufacturers and providers throughout the implementation
- ✓ Health-related costs to patients in terms of unrelated adverse events
- ✓ Medicine-related costs to payers/HTA or providers

Benefits:

- ✓ Broad stakeholder consensus on the high value of early access
- ✓ Significant health gains for patients and providers; strong ROI for manufacturers
- ✓ High savings potential for payers/HTA and providers through cost sharing or offsets

Results: temporal considerations

Cost & benefits: all case-studies combined	Inception & design				Adoption & implementation				Sustainment & maintenance				Wrap-up & closing			
	Pay	Man	Prov	Pat	Pay	Man	Prov	Pat	Pay	Man	Prov	Pat	Pay	Man	Prov	Pat
Costs	Human Resource cost	2	2-3	1-2		2-3	2	1-2		2-3	2	1-2		1-2	1-2	
	Transaction cost	0-1	2			0-1	2	1-1		0-1	2	1				
	Health-related costs								3			3				3
	Medicine-related cost			1		3		1		3		1		3		1
	Other costs	0-1								0-1		1		0-1		1
Benefits	Health related benefits										3	2			2-3	2-3
	Revenue										2-3			0-1		
	Cost savings										2-3		2	2	1	
	Early access										2	2	1-2	1-2	2	1-2
	Spillovers/ pos. externalities	1	0-1			1-2	1			1-2	1	1-2		1	1	1-2
	Other benefits	0-1	1			0-1	0-1				0-1			1-2	2	

- ✓ Trade-off: IPMs balance long-term or later-stage benefits against significant costs across all phases; decision-makers may aim to optimise this balance.
- ✓ Temporary IPMs: Some IPMs are beneficial only until the motivating issue (e.g., long-term uncertainty) is resolved (e.g., through data collection).

Discussion & conclusion

- We developed and applied a new evaluation framework to systematically capture IPM implementation costs and benefits across types, phases, and stakeholder perspectives.
- All IPMs introduced added complexity and higher HR, administrative, and transaction costs across stakeholders and phases, particularly for outcome-based agreements.
- Negotiating outcomes, measurement methods, and data systems (e.g., OBAs, laAPs) imposed greater burdens on payers/HTA, providers, and manufacturers compared to simpler IPM types (e.g., FBRsAs).
- Despite these costs, IPMs enabled earlier access to innovation, improved outcomes, and moderate cost savings through risk-sharing and bundled payments.
- Broader benefits included knowledge spillovers, upskilling, real-world evidence generation, and reputational or policy gains.
- Given their temporal nature, stakeholders should optimise investment—return balance by reducing implementation costs or improving design.
- Overall, IPMs offer flexible means to align affordability, access, and innovation incentives, but require streamlined, time-limited implementation.

References

- HI-PRIX HORIZON. Pay for Innovation Observatory. Published online 2023. <https://p4i.hi-prix.eu/en/about>
- Fox J, Watrous M. Overcoming Challenges Of Outcomes-Based Contracting For Pharmaceuticals: Early Lessons From The Genentech–Priority Health Pilot. Health Affairs Forefront. Published online 2017. doi:10.1377/forefront.20170403.059442.
- Jørgensen J, Hanna E, Kefalas P. Outcomes-based reimbursement for gene therapies in practice: the experience of recently launched CAR-T cell therapies in major European countries. Journal of Market Access & Health Policy. 2020;8(1):1715536. doi:10.1080/20016689.2020.17155364.
- Iglesias-López C, Agusti A, Vallano A, Obach M. Financing and Reimbursement of Approved Advanced Therapies in Several European Countries. Value in Health. 2023;26(6):841-853. doi:10.1016/j.jval.2022.12.014
- McElwee, F, Cole, A., Kallappan, G., Masters, A., & Steuten, L. (2025). Alternative Payment Models for Innovative Medicines: A Framework for Effective Implementation. Applied Health Economics and Health Policy, 1-15.
- Avsar, T. S., Elvidge, J., Hawksworth, C., Kenny, J., Németh, B., Callenbach, M., ... & Dawoud, D. (2024). Linking Reimbursement to Patient Benefits for Advanced Therapy Medicinal Products and Other High-Cost Innovations: Policy Recommendations for Outcomes-Based Agreements in Europe. Value in Health, 27(11), 1497-1506.
- Public Health Agency of Sweden. Availability to Antibiotics of Particular Importance; 2023. <https://www.svehi.se/engelska/for-press/publication-2023-matosh/availability-of-antibiotics-of-particular-importance/>
- Preckler, V., & Espar, J. (2022). The role of indication-based pricing in future pricing and reimbursement policies: a systematic review. Value in Health, 25(4), 666-675.
- Cole, A., Neri, M., & Cookson, G. (2023). Payment models for multi-indication therapies. Online.(Accessed July 2022).
- Moulin JQ, Dickson KS, Stadnick NA, Rabin B, Aarons GA. Systematic review of the Exploration, Preparation, Implementation, Sustainment (EPIS) framework. Implementation Sci. 2019 Dec;14(1):1.
- Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health. 1999 Sep;89(9):1322–7.
- Feldstein AC, Glasgow RE. A Practical, Robust Implementation and Sustainability Model (PRISM) for Integrating Research Findings into Practice. The Joint Commission Journal on Quality and Patient Safety. 2008 Apr;34(4):228–43
- Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review. Front Public Health. 2019 Mar 29;7:64.