

# **Taxonomy of Risk-Sharing Agreements**

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INSEAD Healthcare Management Initiative  
[www.insead.edu/hmi](http://www.insead.edu/hmi)  
[hmi@insead.edu](mailto:hmi@insead.edu)

Written by Ridhima Aggarwal, The Salmon and Rameau Research Programme Manager with the Healthcare Management Initiative, under the supervision of Stephen E. Chick, Novartis Chaired Professor of Healthcare Management and Professor of Technology and Operations Management, both at INSEAD.

Risk-sharing arrangements (RSAs), also known as managed entry agreements (MEAs), are often categorized as financial/non-health outcome or health outcome-based<sup>1</sup>. RSAs have been predominantly adopted in the pharmaceutical sector, though they are gaining traction also in the medical device industry, particularly in areas such as diabetes.

### **Financial or finance-based schemes**

These non-health outcome-based schemes apply cost containment strategies without accounting for health outcomes or directly linking reimbursement to cost-effectiveness. Examples include:

- **Patient access schemes (PASs)**<sup>2</sup>, implemented at the patient level, involve the provision of health technologies at a lower price or for free, so as to improve value of the technology or patient access allowing more patients to take the therapy. In addition, spending limits may be set for a certain medications, and patients may receive free treatment once that cap is reached.
  - **Price cap**<sup>3</sup> schemes control financial impact at the individual patient level. Drugs are provided free once patients reach a fixed utilization limit.
  - **Dose cap**<sup>3</sup> is a form of a patient access scheme where manufacturers and payers agree on a pre-determined level of consumption, and manufacturers are responsible for any additional costs incurred beyond this limit. NICE in the UK agreed on a dose capping scheme over Lucentis for macular degeneration, where the NHS would pay a maximum of 14 injections of per eye with Novartis to bear the cost if any more were needed. The manufacturer thus assumes the risk that most patients will not need more than 14 injections.
- Under **price volume agreements (PVAs)** or budget impact schemes implemented at the population level, financial expenditure is controlled through manufacturer compensation. The unit cost of an innovative technology is linked to total volume purchased, and prices are often reduced for additional units needed beyond this threshold. For example: in the UK, patient consumption is tightly controlled for a number of drugs appraised by NICE, e.g. Herceptin, Gleevec, Rituximab; and in Italy, drug prices are negotiated by the central government, but regional offices closely monitor patient volume.
  - **Payback policies** are a form of PVAs, whereby manufacturers must pay back a portion of their revenue, if health expenditure exceeds a pre-determined budget ceiling.
  - **Discounts or rebates**, also forms of PVAs, require manufacturers and pharmacists to payback a proportion of their revenue if drug spend surpasses a pre-set limit. In absence of rebates, current and future rights to high prices would be waived.

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<sup>1</sup> The following sources were referenced to develop this taxonomy: Performance-Based Risk-Sharing Arrangements-Good Practices for Design, Implementation, and Evaluation: Report of the ISPOR Good Practices for Performance-Based Risk-Sharing Arrangements Task Force, <http://www.ispor.org/TaskForces/documents/Performance-based-Risk-Sharing-Guidelines.pdf>; and Linking Payment to Health Outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers, <http://www.sciencedirect.com/science/article/pii/S0168851010000515>.

<sup>2</sup> In the UK, the term 'patient access schemes' refers to risk-sharing schemes overall, and hence includes both finance- and outcomes-based agreements.

<sup>3</sup> Price cap and dose cap may also be referred to as utilization caps.

### **Health outcome-based schemes**

Reimbursement is tied to clinical outcomes in real life. Price adjustments or refunds are mandated when a technology fails to deliver the desired health outcomes in practice. Examples include:

- **Coverage with evidence development (CED)** refers to when reimbursement is granted to patients enrolled in a controlled environment, i.e. a scientific study. Coverage is funded for eligible patients participating in a research study designed to generate more robust clinical evidence. The main aim is to address uncertainty identified during the drug evaluation process; may not be linked to reimbursement or a discount. For example, the Medicare Evidence Development and Coverage Advisory Committee suggested that Centre for Medicaid and Medicare services (CMS) collect outcomes data post-approval outcomes data on cancer ‘vaccine’ Sipuleucel-T (provenge) through registries to help identify which patients would benefit most from the therapy<sup>4</sup>.
- Conditional-coverage agreements imply that price and reimbursement are temporarily granted, but failure to achieve set targets (i.e. particular indication, defined patient population) may result in price and reimbursement changes and/or rebates. Manufacturer may have to pay back excess.
  - **Conditional treatment continuation** schemes are targeted only for individual patients and linked to short-term goals, such as tumor reduction or cholesterol levels. In Italy, for example, patients on an Alzheimer’s drug are evaluated at 3 months for effectiveness, and if outcomes are favorable, they continue to receive treatment for a maximum of two years, with reimbursement from the national health service.
- Performance-based
  - **Outcomes guarantee** policies provide insurers with guarantee on the monies they spend. If a given treatment does not lead to desired outcome in patients based on a list of clinical endpoints, the manufacturer must cover the cost retroactively reimbursing the payer or for covering same amount of costs for another patient. Rebates may also be offered when desired outcomes are not achieved. Manufacturers must hence have instruments in place to closely monitor patients. E.g. Following NICE’s initial rejection, UK NHS agreed to pay for anticancer drug, Velcade (bortezomib), only when the treatment was effective as measured by the rate at which tumors shrink. The manufacturer must provide a rebate for the cost of treatment if patients do not respond to Velcade<sup>5</sup>. UK multiple sclerosis (MS) scheme addresses uncertainty by observing a cohort of patients and linking drug price to the cost/quality-adjusted life year (QALY) threshold.

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<sup>4</sup> For more information, see <http://jnci.oxfordjournals.org/content/early/2011/02/08/jnci.djr041.full>.

<sup>5</sup> This particular RSA includes elements from multiple schemes. In addition to outcomes guarantee, conditional treatment continuation also applies. Tumour response is evaluated after 4 cycles of treatment, and if patients do respond, they continue to receive additional therapy which is covered by the NHS.