Performance-Based Risk-Sharing Arrangements for Devices and Diagnostics in the United States: A Systematic Review

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Definition

PBRSAs can be defined as arrangements between a payer and a pharmaceutical, device, or diagnostic manufacturer, where the level or continuation of reimbursement is linked to the real-world performance of medical products (i.e. health or economic outcomes), in a defined patient population over a specified period of time.

General enthusiasm in PBRSA

01

Uncertainty

in the real-world performance (effectiveness and safety)

Cost

pressures on manufacturers and payers

02

03

Emergence

of new medical technologies

Expansion

of real-world data for FDA approvals

04

Devices and diagnostics: what's new?

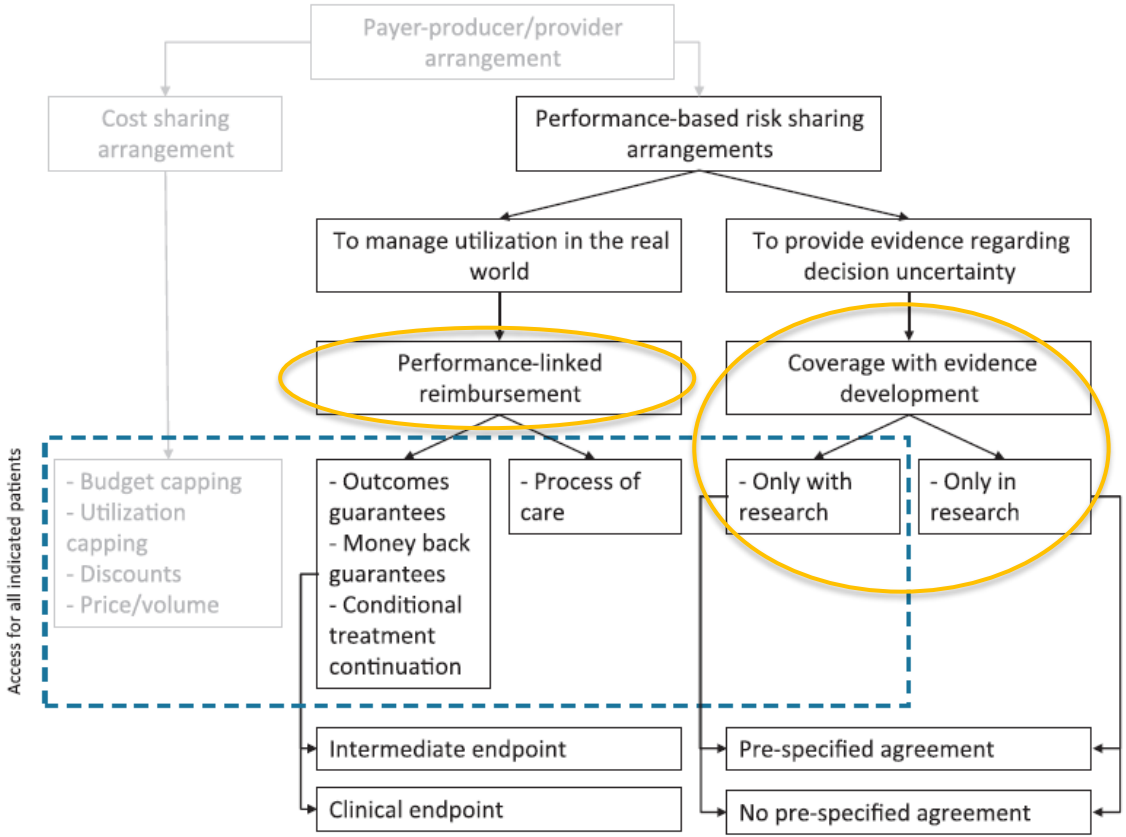
- Different payer dynamics
- Potential short-term process related outcomes
- Lower budget impacts, different IP, patent environments
- Less well-developed evidence base at the time of market entry

Methods

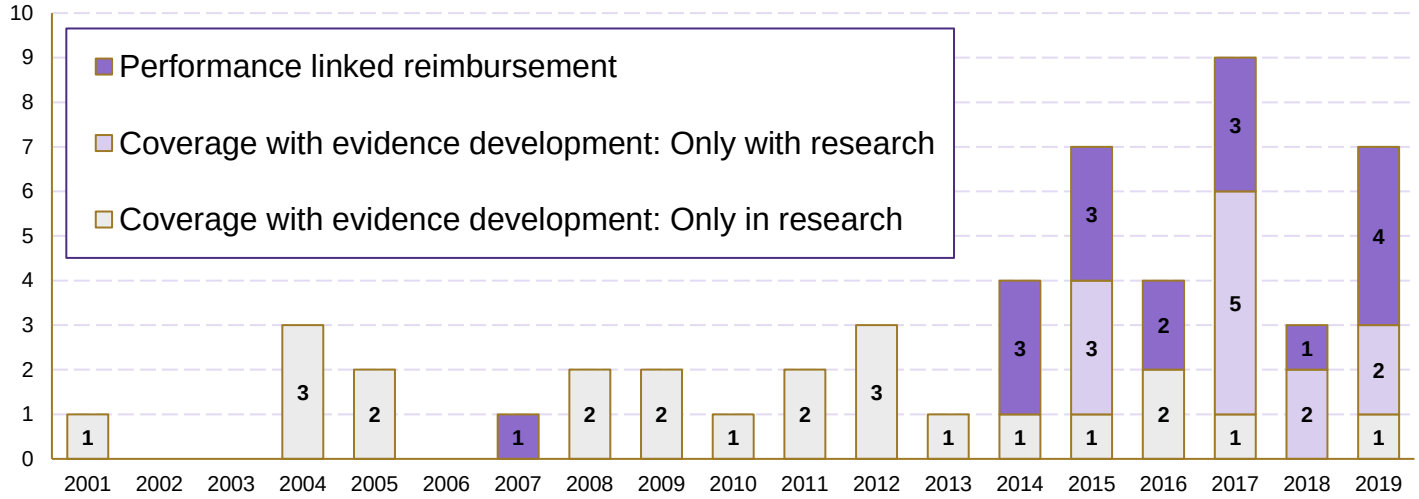
Source	PubMed, Google, payer and reimbursement agency websites, industry websites, University of Washington Performance Based Risk Sharing Database
Time period	January 2001 to September 2020
Key words	“outcomes-based”, “value-based”, “coverage with evidence development”, “performance-based”, “risk-sharing” in combination with “device” or “diagnostic

Types of Arrangement

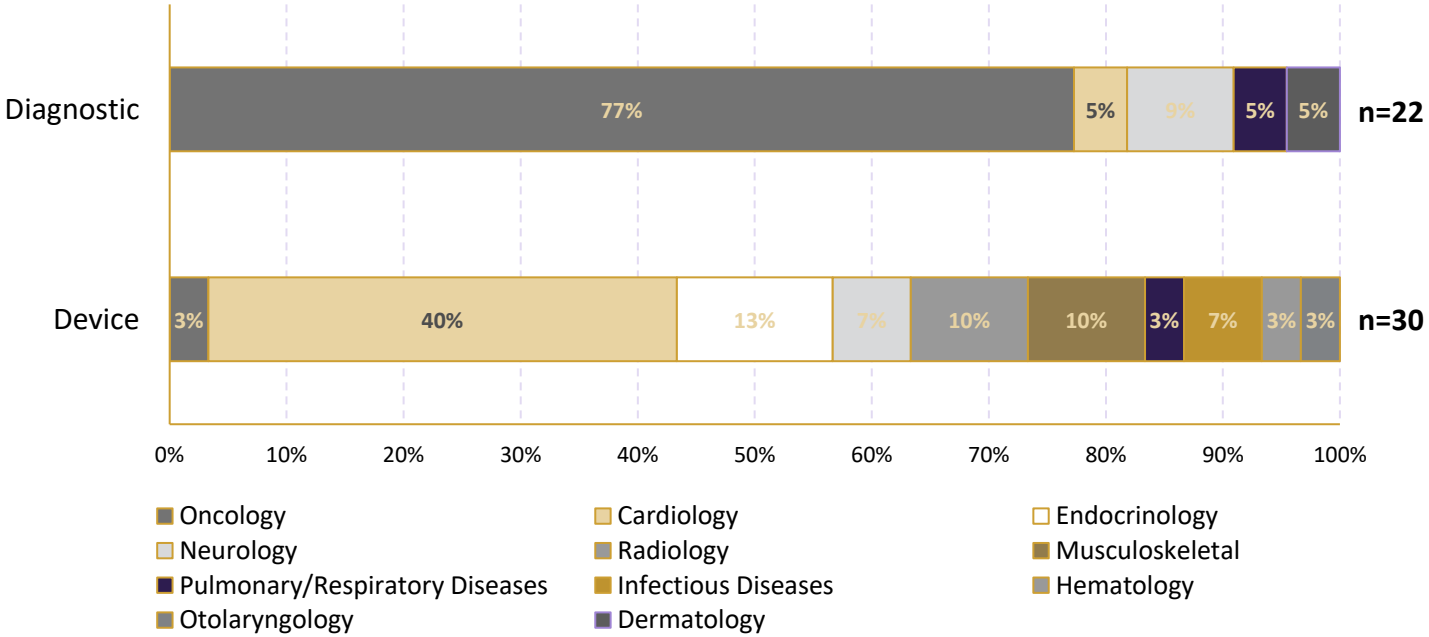
ISPOR Task Force Taxonomy



PBRSAs by arrangement categories over time



Arrangements by therapeutic areas



Diagnostics examples

Product	Year	Arrangement Description
Oncotype DX® Breast Cancer Assay, Genomic Health; United Healthcare (UH)	2007	UH agreed to reimburse the OncotypeDx test for 18 months while it and Genomic Health monitor the results. If the number of women receiving chemotherapy exceeds an agreed upon threshold, even if the test suggests they do not need it, the insurer will negotiate a lower price.
DecisionDx®-UM, Castle Bioscience, Inc; Palmetto GBA	2017	The contractor believes a prospective registry currently in progress will generate sufficient data to demonstrate improved patient outcomes. Continued coverage of this assay will depend on semi-annual review of interim data and publications demonstrating the above clinical utility.

Medical device example

Minimed™ 670G System by Medtronic

BUSINESS

Medtronic, Blue Cross sign glucose monitor deal linked to patient outcomes

Some patients could end up paying less for monitor.

By Joe Carlson Star Tribune | APRIL 6, 2019 — 12:01AM

Medtronic is striking a first-of-its-kind agreement with Minnesota's largest health plan in which the device maker will pay back the insurer if patients using a specific Medtronic diabetes device don't see their blood sugar levels stay within an acceptable range.

The "value-based" arrangement, to be unveiled Monday, is designed to make it easier for Blue Cross and Blue Shield of Minnesota members to obtain and use a Guardian Connect continuous glucose monitor from Medtronic.

June 26, 2017 01:00 AM

Medtronic inks outcome-based contract with Aetna for insulin pumps

ALEX KACIK

TWEET SHARE SHARE EMAIL PRIN

Medtronic and Aetna announced a new outcomes-based agreement Monday for Type 1 and Type 2 diabetes patients who transition to Medtronic's insulin injectors, signaling the continued growth of value-based contracts throughout the industry.

Medtronic will pay Aetna rebates for patients who switch from multiple daily injections of insulin to Medtronic's insulin pump and their health does not hit specified outcomes, according to the agreement that aims to increase accountability and lower the cost of care.

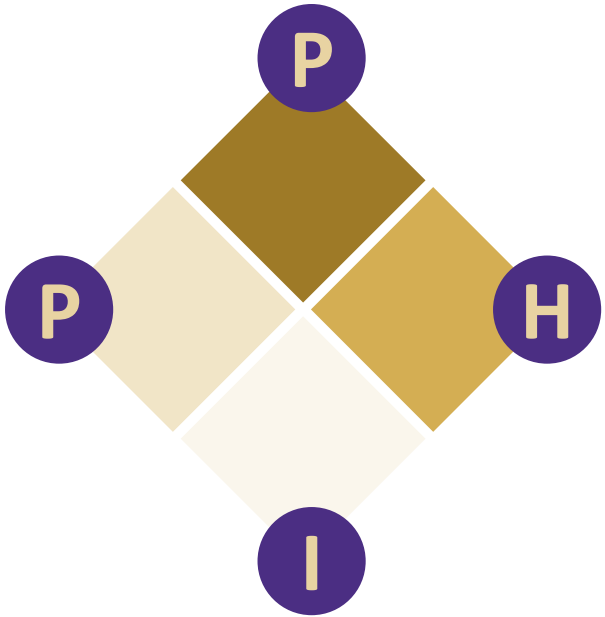
Diverse payers

Public payer

Centers for Medicare and Medicaid Services

Private insurance

Atena, Blue Cross and Blue Shield, United Healthcare, Capital District Physicians' Health Plan, etc



Hospital

Temple University Health System, Jefferson Health, Lifespan, etc

Integrated healthcare delivery system

Fairview Health Services, Atrium Health, Sanger Heart & Vascular Institute

Key Considerations and Challenges

- Definitions and study designs
  - Clearly defined outcomes
  - Follow-up period
- Data collection
  - Real-world data (i.e., claims, EHR, registry, etc)
  - Hospital studies
  - Innovative digital health programs
- Evaluation and improvement
  - Explore impact of arrangements
  - Establish clear process flow

Limitations

- No confidential cases
- Incomplete data for arrangements made in 2019-2020
- Level of interests in PBRSAs may vary between manufacturers and payers

Conclusion

1. The adoption of PBRSAs for devices and diagnostics have continued to gain enthusiasm in different payers in the US.

2. PLR, CED – only with research, and CED – only in research are the major types of arrangements for devices and diagnostics, with the level of activity differing between public, private payers and hospitals.

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Thank you!

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