

NEW DIGS

FoCUS

Financing and Reimbursement
of Cures in the US

Managing Gene Therapies: The Orphan Reinsurer and Benefit Manager (ORBM)

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MIT CENTER FOR BIOMEDICAL INNOVATION



I have no conflicts to report...

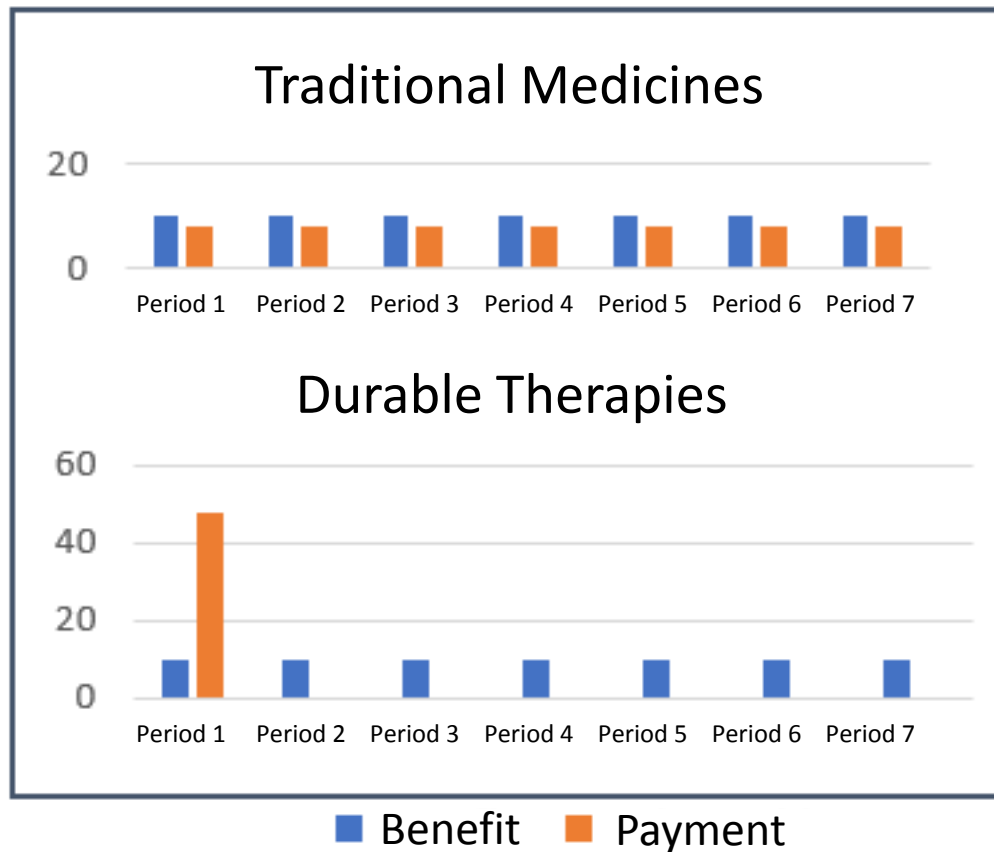
Overview

- FoCUS: Who we are
- Overview of the Issues...
- The “ORBM”

FoCUS: Who We Are...

- “Financing and Reimbursement of Cures in the US”
 - Understand impacts of durable therapies
 - Help the (financing) system catch up to the science
- Neutral convener seeking:
 - Access for patients
 - Appropriate protection for payers and providers
 - Sustainable innovation
- Consortium of > 50 organizations

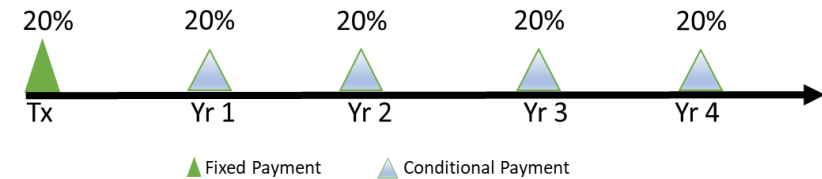
Financial Challenges of Durable Therapies



- Performance Risk
- Payer Disconnect (Mobility)
- Actuarial Risk (+Surge)

Two Categories of Solutions

- Individual-based solutions
 - Spread payments over time
 - Performance-based agreements
- Population-based solutions
 - Reinsurance/Stop-loss
 - Risk Pools
 - Orphan Reinsurer and Benefit Manager (ORBM)

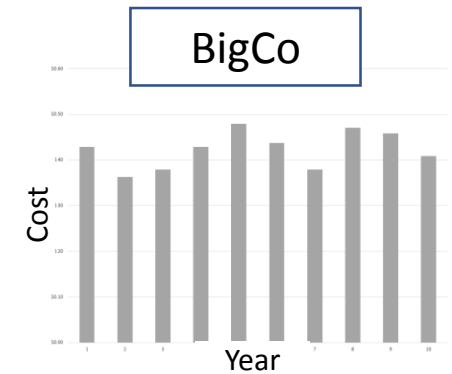
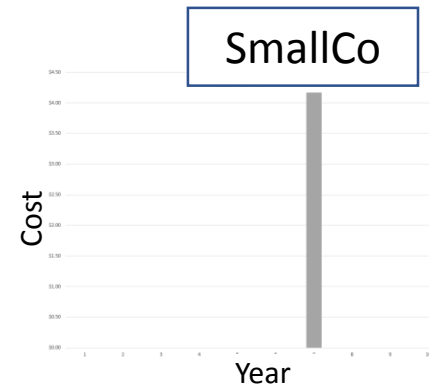


Performance-Based Agreements

- Primarily address “Performance Risk”:
 - Milestone or rebate when uncertainty resolves
 - Metrics? Mobility?
- Challenged (US) by Medicaid Drug Rebate Program:
 - Low price for any patient sets a high rebate (“best price”)
 - Update or mitigate?

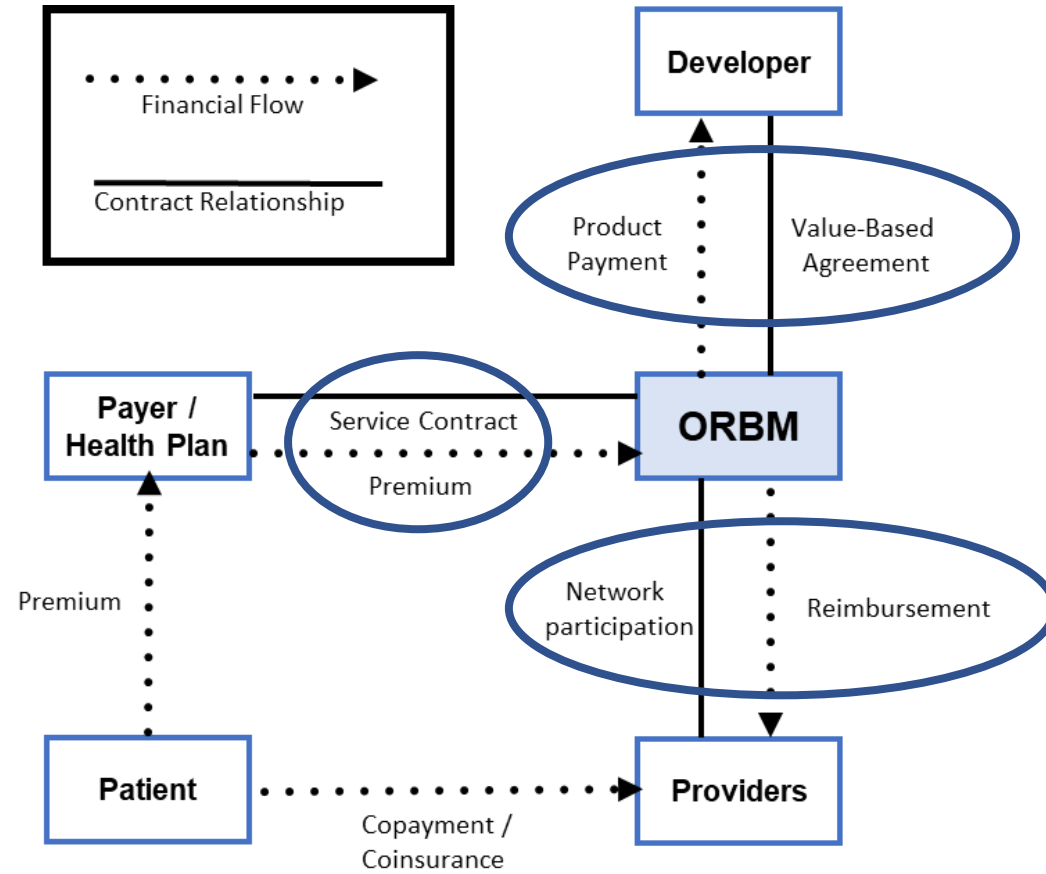
Population-Based Solutions

- Financial Challenges
 - Cash
 - Accounting
- Operational Challenges
 - Disease expertise
 - Provider networks



→ Carve-outs, COEs (mental health, CF, transplant centers)

ORBM as an Intermediary



Challenges Mitigated by ORBMs

- Financial challenges
 - Risk / reinsurance
 - Claim adjudication and payments
 - Financial engineering
- Operational challenges
 - Contracting with developers (risk sharing?)
 - Patient and utilization management
 - Network/Disease management
 - Data management

Some ORBM Variants...

- Disease Scope
 - Breadth
 - Class
 - Rarity
- Benefits Offered
 - Durable treatments
 - Conventional disease treatments
 - Patient carve-out

What can't an ORBM Do?

- Adverse Selection Issues
- Affordability



An ORBM...

- Is an intermediary that:
 - Consolidates risk
 - Creates operational efficiency
- Comes in many flavors (ORBM and payer customization)
- Can arise from
 - Existing players
 - New entities