

FoCUS Financing and Reimbursement of Cures in the US

Focus of FoCUS**On**

Creating **precision financing solutions** for therapies with large, upfront, acute costs whose benefits accrue over time

**Not on**

Assessing or setting value, or negotiating specific prices for specific products



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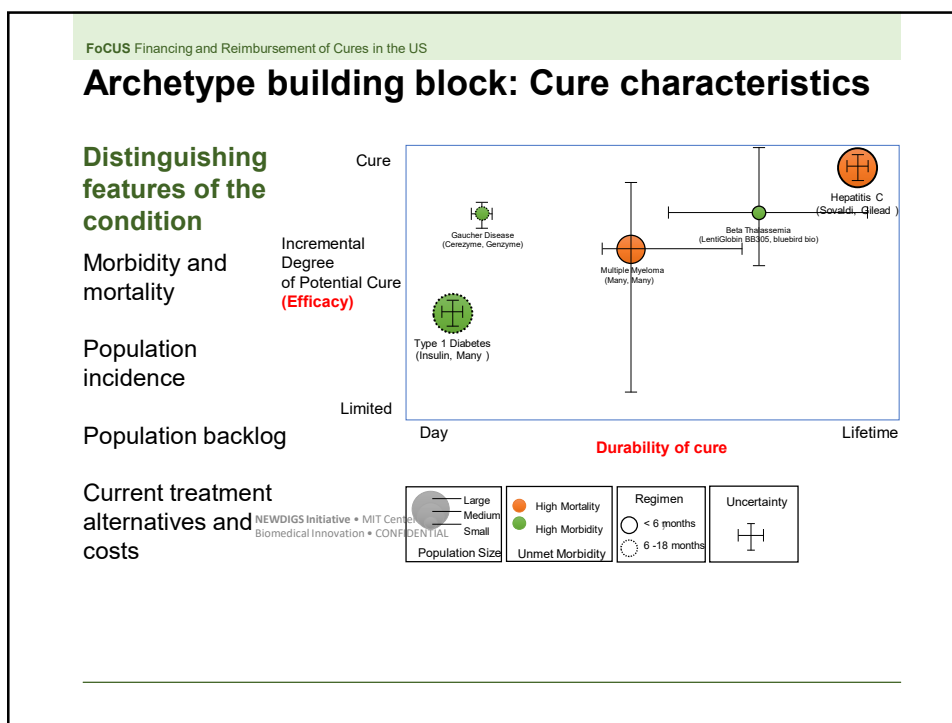
How do we think about Value (NOT price setting)

$$\text{Value} = \frac{\text{Benefits}\Delta}{\text{Costs}\Delta}$$

Δ

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Challenges Vary by Payer Type And Cure Archetype

- No “one-size” solution, even within therapeutic areas or product classes

Cure Archetype	Private		Public	
	Self-Insured Employers	National Insurers	Medicare	Medicaid
Oncology	Perf, A	Perf	Perf	Perf, A
Novel Breakthrough	A, Perf, Pmt	Perf	Perf	A, Perf, Pmt
Orphan disrupters	A, Perf, Pmt	Perf	Perf	A, Perf, Pmt
Quantum Leaps	Pmt, Perf, A	Pmt, Perf	Pmt, Perf	Pmt, Perf, A

A: Actuarial Risk Timing Perf: Performance Risk Pmt: Payment

- Financial tools (solution patterns) can help manage risk and flow of money—“precision financing”

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Three Precision Financing Solutions To Meet The Challenges

Short-term milestone-based contracts

- <2 year duration
- Specified rebate payments tied to early outcome

Multi-period performance-based annuities

- > 2 years (likely 3 to 5)
- Payments spread out over contract period
- Tied to performance over time

Orphan Reinsurer and Benefit Manager (ORBM) and Risk Pools

- Carve out risk and management of novel breakthroughs

Solutions must be customized for the therapy/disease AND satisfy each stakeholder

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Regulatory/Policy

- **Medicaid drug price reporting and rebate** need adapting to multi-year performance structures, allow greater risk taking e.g. weighted assessments vs single case
- **Anti-Kickback Statute** to define explicit safe harbor (WIP)
- **FDA communication guidelines to enable appropriate performance metrics** Clinical trial endpoints often not practical for clinicians or present in payer data systems
- **HIPAA** to enable data visibility to all involved parties
- **Insurance regulations** to all deductible and co-pay waivers (Federal and State)

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