Financing and Reimbursement of Cures in the US
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FoCUS: Multi-stakeholder group dedicated to making innovative cures accessible to patients and sustainable to ALL stakeholders
FoCUS Stakeholders’ Path from Discovery to Delivery

- >50 organizations & 150 individuals engaged
- Multi-stakeholder participation: Patients, providers, developers, payers, and policy

I. Elucidation (April 2017)
II. Pressure Testing
III. Dissemination & Implementation Planning

April 2017 October 2017 April 2018 October 2018

Pilot & Scale
Inform & Influence
Measure & Model
Extend, Evolve & Deepen

Emerging Durable Therapies Driving New Payment Models

Three financial challenges exacerbated

Payment timing
One-time high cost

Performance risk:
Effectiveness & durability

Actuarial risk:
Likelihood of encountering a case
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

How do we think about Value (NOT price setting)

Value = \frac{Benefits - Costs}{\Delta}
**Archetype building block: Cure characteristics**

- **Distinguishing features of the condition**
  - Morbidity and mortality
  - Population incidence
  - Population backlog

- **Current treatment alternatives and costs**

- **Cure characteristics**
  - Incremental degree of potential cure (Efficacy)
  - Durability of cure
  - Lifetime

- **Challenges Vary by Payer Type And Cure Archetype**
  - No “one-size” solution, even within therapeutic areas or product classes
  - Financial tools (solution patterns) can help manage risk and flow of money—“precision financing”
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)