

## NEW DIGS

# FoCUS

Financing and Reimbursement  
of Cures in the US

## RESEARCH BRIEF

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FoCUS Project  
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**An Orphan Reinsurer Benefit Manager (ORBМ) could address the financial challenges (payment timing, therapeutic performance risk, actuarial risk), created by durable/potentially curable gene and cell therapies especially for smaller insurers and self-insured employers.**

Any individual durable/potentially curable orphan therapy may be managed within the existing healthcare financing system but collectively they may prove challenging. This is particularly true for smaller Payers with limited ability to manage large upfront payments, therapeutic performance risk and/or actuarial risk. Using orphan disease therapies as a proof of concept, the FoCUS Project envisions **Orphan Reinsurer Benefit Managers** as a precision financing solution to address the financial challenges.

ORBMs could integrate healthcare financing and management by clinical and financial risk to:

- Increase care delivery consistency and efficiency via concentrated care networks;
- Share risk across healthcare stakeholders;
- Create scale efficiencies for care coordination, contracting and financing management.

We expect multiple ORBMs to emerge from existing insurers or pharmacy benefit managers, to be formed *de novo*, or even to be created by consortium or government action. Each ORBM would select the range of services to offer, diseases to cover, and risk to bear.

### KEY FEATURES OF THE FULL SERVICE ORBM

#### 1. Carve-out & Pool risk

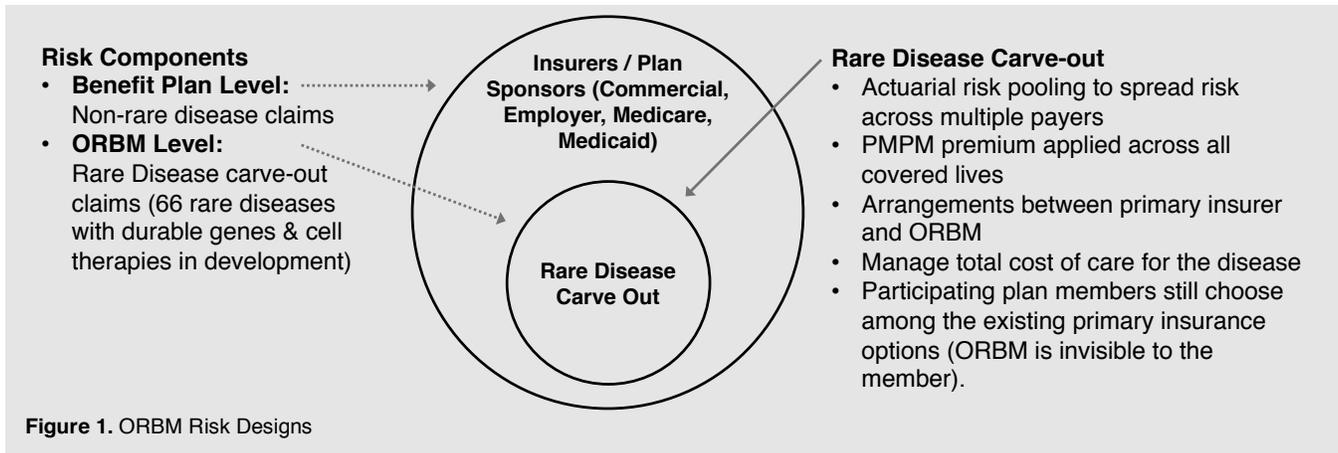
- Carve-out 66 orphan diseases (where there are durable/potentially curable gene

### KEY TAKEAWAYS

- ORBMs integrate healthcare delivery and financing to mitigate three principle financing challenges (payment timing, therapeutic performance risk and actuarial risk).
- Targeting orphan diseases with durable therapies in development as a proof of concept, ORBMs could offer a sustainable means to carve-out and pool risk; deliver efficient contracting and payment among Payers, Providers & Developers; and establish comprehensive disease care coordination services.
- Payer segments most vulnerable to the 3 financing challenges may benefit most from the ORBM, such as self-insured employers, smaller insurers, and managed Medicaid.

therapies in development) and provide comprehensive total disease care (medical and pharmacy)

- Actuarial per member per month (PMPM) premium applied across all covered lives and capitation of costs provides improved Payer predictability
  - Mitigates payment timing and actuarial risk
- #### 2. Contracting & Payment
- Establish the provider network and contract management with developers and providers
  - Customize value-based agreements based on unique uncertainties (financial or outcome-based) introduced by each new ...



- ... durable therapy leading to contracting and execution efficiencies
- Could act as a financier and provide asymmetric payment patterns to developers, payers and providers. Perhaps even provide patient financing or assistance
  - Mitigates therapeutic performance risk

### 3. Care Coordination Services

- Comprehensive disease management programs tailored to disease and patient needs
- Manage care coordination and outsource components with greater expertise due to scale
- Collaborate with Patient Support Groups on educational materials and research initiatives where synergies can be created
- Mitigates therapeutic performance risk

### CUSTOMIZING THE ORBM

The ORBM framework can be customized for payer segments, even each client, by varying:

- Pool threshold (first dollar or attachment point)
- Diseases to include
- Care coordination services to include and the level of those services
- Scope of costs to cover from gene therapy costs only to complete patient carve-out

### ORBM FINANCIAL FEASIBILITY AND SUSTAINABILITY

Preliminary analysis suggests that an ORBM focused on the orphan diseases with durable therapies in development estimated 0.5% to over 4% of total healthcare spend. This is comparable to existing healthcare carve-outs in transplantation and mental health which also have high payer incidence uncertainty and risk exposure and overall total healthcare spend ranging from 1%<sup>1</sup> to 5.3%<sup>2</sup> spend respectively.

<sup>1</sup> Hanson S., Bentley T. 2014 U.S. organ and tissue transplant cost estimates and discussion. Milliman, Inc. <http://www.milliman.com>. Published December 30, 2014.

<sup>2</sup> Substance Abuse and Mental Health Services Administration. Projections of National Expenditures for Treatment of Mental and

### ORBM VARIETIES

A full service ORBM is the most comprehensive design. Depending on the specific payer segment and durable therapy characteristics, ORBMs could form alternative subsets to address gaps in payment financing, contracting and/or care coordination services in a plug and play model.

#### Alternative plug-and-play scenarios:

- Health Insurer manages contracting and care coordination services (without carve-out or risk pool)
- Pharmacy Benefit Manager (PBM) positions itself as a risk bearing entity and partners with a Reinsurer for actuarial expertise to manage the financial implications of value-based contracting
- Specialty Pharmacy and PBM negotiate a fee with developer and bill PBM clients cost of therapy without a mark-up (white bagging) and leverage utilization management tools to track patient outcomes.

### ABOUT FOCUS

The MIT NEWDIGS consortium FoCUS Project (Financing and Reimbursement of Cures in the US) seeks to collaboratively address the need for new, innovative financing and reimbursement models for durable therapies that ensure patient access and sustainability for all stakeholders. Our mission is to deliver an understanding of financial challenges created by durable therapies leading to system-wide, implementable precision financing models. This multi-stakeholder effort gathers developers, providers, regulators, patient advocacy groups, payers from all segments of the US healthcare system, and academics working in healthcare policy, financing, and reimbursement.

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Substance Use Disorders, 2010–2020. HHS Publication No. SMA-14-4883. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.