

# NEWDIGS

at Tufts Medical Center

## Next Generation Payment Innovation Roundtable Proceedings



### A framework to promote broader adoption of payment innovation

As pharmaceutical companies launch novel products and payers strive to manage treatment costs and affordability, patient access can suffer. Payment innovations such as multi-year performance-based agreements, warranties, and subscriptions have emerged in recent years to mitigate these tensions, independent of price setting.

Most of these models have been introduced in response to launches of durable cell and gene therapies, which provide transformative, even ‘curative’ benefits over multiple years, but carry uncertainties regarding effectiveness, durability and numbers of eligible patients, in addition to high upfront costs. Multiple stakeholders including pharmaceutical developers, payers, stop-loss and reinsurance providers, and financial startups have sought to mitigate these risks by engaging in alternative financing solutions.

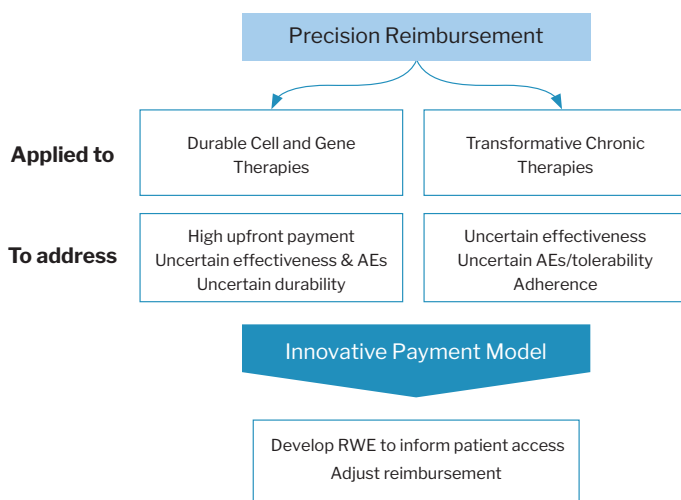
Now stakeholders are considering the use of these payment innovations for transformative chronic disease therapies, and for therapies in more prevalent conditions. Like durable cell and gene therapies, these treatments possess significant uncertainties regarding potential patient benefits, the eligible patient population that will choose treatment, and the significant payer financial impact.

Accelerating success in designing and implementing payment innovation would benefit from a multi-stakeholder framework that:

- Improves patient appropriate access to beneficial therapies
- Describes practical principles for payment innovation for all stakeholders
- Identifies critically needed capabilities and actions for implementation
- Spurs targeted multi-stakeholder action to catalyze change.

These proceedings summarize the NEWDIGS Initiative Roundtable event on September 21, 2022 that gathered payer and biopharmaceutical views on a payment innovation framework for novel therapies.

## Payment Innovation Application



### The need for payment innovation

Appropriate, timely patient access can be inhibited by stakeholder incentive misalignment as each pursues their legitimate goals within their constraints. Payment innovation could both reduce that misalignment and improve goal attainment across stakeholders. To do so, payment innovations must address unmet challenges among stakeholders. These include:

- **Therapeutic risk:** the performance risk (e.g., long-term durability and safety) associated with novel cell- and gene therapies in the real-world remains a key concern for payers. Payment innovation addresses this uncertainty by ensuring payments are aligned to patient benefits.
- **Actuarial risk:** unpredictability in the size of a likely patient population and subsequent surges in treatment costs can create financial strain that would ideally be leveled by payment innovation.
- **Operational efficiency:** resources for the implementation of payment innovation are often not available. Performance-based agreements, for example, can quickly become complex and require an integrated operational and legal network to collect and adjudicate patient data (e.g. claims/patient data).
- **Evidence creation:** standardized collection of post approval real-world data to reduce uncertainties and ensure patient benefits is a key unmet need, especially when labeled indications are broader than participants evaluated in the clinical trials.

Today, these four challenges induce patient access issues as stakeholders struggle to resolve them before treatment, with limited evidence. Payment innovations, especially those employing value-based outcomes features, can mitigate these challenges after treatment, with real-world patient benefits observations. Thus, NEWDIGS envisions payment innovation occurring independently of the determination of the initial product value/price per dose. Furthermore, NEWDIGS envisions flexible payment innovation

mechanisms that may be implemented among subsets of stakeholders (such as individual payers and pharmaceutical companies). However implemented, NEWDIGS suggests the impacts must be considered for all stakeholders in the design: patients; providers; pharmacies and other channel participants; payers; and pharmaceutical companies.

### Core principles for payment innovation

To address these four challenges the Roundtable agreed on five payment innovation principles.

1. **Ensure patient-centric, equitable access.**
  - Employ quality of life outcome metrics whenever possible. When clinical metrics or proxies are necessary, patient relevance should be explicit.
  - Payment innovation should not delay therapy access upon launch, or in clinical practice.
  - Payment innovation should not increase, and even seek to reduce, healthcare disparities.
2. **Connect access and reimbursement to patient benefits received.**
  - Address therapeutic risk with value-based payment innovations that adjust net payments based on metrics in the reimbursed patients.
  - Align incentives across stakeholders, including patients and providers, to ensure patient access and that all share in the financial benefits of the therapeutic payment innovation.
3. **Reduce financial volatility.**
  - Minimize payer actuarial risk volatility and payment variability from value-based payment innovations through population pooling, rebates/payments over time or other mechanisms.
  - Lessen payment surges for patients and providers through payment plans or other approaches.
4. **Achieve operational efficiency.**
  - Reduce payment innovation administration costs while maintaining accountability and flexibility.
  - Simplify contracts and adjudication processes to use attainable and timely metrics.
5. **Design to learn over time.**
  - Share best practices regarding payment innovation design and implementation
  - Leverage payment innovation results as another source of real-world evidence whenever possible.

### System changes to catalyze payment innovation

Payment innovation requires new capabilities within the healthcare industry and evolving regulations. The Roundtable agreed on two core changes that would catalyze payment innovation: agreement over outcomes metrics and tracking platforms to collect data across multiple contracts. Recent federal policy changes are a positive step toward for payment innovation, although stakeholders remain hesitant to fully engage.

### Advance metrics and the platforms to collect them

For payment innovations that include value-based features, patient-centric metrics that can be practically collected need development. While claims-based proxies may suffice in the short term, in the long-term stakeholders aspire to collect robust patient-reported quality-of-life metrics in addition to efficacy and safety outcomes. The metric development process should use patient-driven, stakeholder inclusive processes, perhaps by therapeutic areas. Further, to enable efficient administration, metrics for payment innovation must be inexpensive, reliable, and collected in a timely manner.

To facilitate broad payment innovation adoption, incentives for metrics tracking platforms that operate across multiple contracts and therapeutic areas need creation. Existing stakeholders often possess the data, emerging organizations increasingly consolidate and disseminate the data, and technologies from health information exchanges to tokenization enable data flow. Integrated delivery networks (IDNs) demonstrate the potential of such platforms within their systems. Increasing incentives would enable inter-organization metrics sharing to address patient mobility challenges, increase population sizes for learning and risk reduction, and gain scale to lower administration costs.

### Federal policy changes are a step forward

New regulations regarding optional reporting of multiple Medicaid best price figures for value-based purchasing (VBP) agreements are a step forward for payment innovation. However, stakeholders remain hesitant to engage in implementation of VBP agreements. This may be due to a lack of education or clarity around the best price regulations or concerns regarding the impact on average sales price (ASP) or average manufacturer price (AMP), which affect the amounts owed under the 340B Drug Pricing Program and the Medicaid Drug Rebate Program. The Roundtable agreed that expecting changes to federal statutes to fully accommodate payment innovation is unrealistic and that there is capability to progress further within the context of current regulations.

### Opportunities for collaborative action

Collaborative activities could catalyze payment innovation implementation by:

1. **Creating a patient-centric framework for value-based contracting.** There was strong interest in moving payment innovation and precision reimbursement towards larger disease populations whilst ensuring value-based contracting remained focussed on patients.
2. **Working with champions/change agents among Consortia participating organizations to help understand payment innovation.** Lack of knowledge about payment innovation impedes systems change and uptake. There is a major need to support payment innovation educational initiatives within and among stakeholder organizations.

3. **Developing a set of functional standards for data collection and sharing, including defining patient-centric health outcomes for key therapeutic areas.** Publication around surrogate or process metrics, such as retrospective analysis of discontinuation (reflective of patient intolerance) or time to treatment switching (reflective of efficacy) is needed.
4. **Supporting group process learning and sharing of best practices.** Resources such as case studies and templates or process methodologies, for use when considering implementation of payment innovations would be invaluable.
5. **Contributing to systems change by suggesting government policy and regulation innovation.** This could include contributions towards refinement of the Medicaid Drug Rebate Program, to enable more payment innovations such as subscription models, and efficient implementation.

### About NEWDIGS

The NEW Drug Development ParadIGMs (NEWDIGS) Initiative at Tufts Medical Center is an international “think and do tank” dedicated to delivering more value faster to patients, in ways that work for all stakeholders. NEWDIGS designs, evaluates, and initiates advancements that are too complex and cross-cutting to be addressed by a single organization or market sector. Its members include global leaders from patient advocacy, payer organizations, biopharmaceutical companies, regulatory agencies, clinical care, academic research, and investment firms.

For more information, visit [newdigs.tuftsmedicalcenter.org](http://newdigs.tuftsmedicalcenter.org).

### GLOSSARY

**Payment innovation:** Contracting arrangements other than straight discount or volume-based rebates, such as warranties, pooling approaches, subscription models.

**Durable therapies:** Cell and gene therapies providing an expected benefit duration of at least 18 months from a single administration. Examples include CAR-T cell therapies and AAV-based therapies such as Zolgensma, but not vaccines.

**Chronic therapies:** Therapies administered on a recurring basis over time to treat an on-going condition. Includes small molecule, biologic, cell, and gene therapies for conditions ranging from ultra-orphan to large population, including oncology.