

Precision Reimbursement Working Session

Design Lab

November 15, 2022



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Precision Reimbursement Team Meeting Participants

Name	Organization	
Mark Trusheim	NEWDIGS	Precision Reimbursement Team Lead & Meeting Facilitator
Tsega Meshesha	NEWDIGS	Scribe
Lucas De Breed	August Care	
Karen Geary	NEWDIGS	
Liz Lewis	Takeda	
Silvio Pitter	Takeda	
Ron Potts	6 Degrees Health & Kaiser Permanente	
Casey Quinn	PCORI	



Team Meeting & Report Out Timing

1:45-3:15 pm Team Meeting

- 10 minutes – Introductions and presenter selection
- 70 minutes – Discussion
- 10 minutes – Presentation coordination

Notes and instructions

- **Each team will need to pick a presenter for the Report Out session that follows the team meeting session. *Please do this first!***
- **Each team meeting will be facilitated by the Team Lead and have a pre-selected scribe(s).**
- **At 3:15 pm, please send the presentation to the email hyperlinked on the last slide.**

3:15-3:30 pm Break

3:30-4:30 pm Team Reports and Group Discussions

Per team:

- 10 minutes – report out
- 5 minutes -- Q&A



Agenda

- Precision Reimbursement Roundtable and Framework
- Selecting Future Case Studies
- Lipids Management Webinar and Community of Practice



Precision Reimbursement Goal: Improved Patient Outcomes

- ***Harnessing payment models to creatively incentivize clinical use of therapies based on Real-World Evidence (RWE)*** to improve patient outcomes, enhance healthcare system sustainability, and account for value created by upstream innovation.
- ***Creating scalable, Precision Reimbursement models*** capable of implementing many RWE findings simultaneously while nimbly adapting to each finding's characteristics and each stakeholder's needs.
- ***Contributing RWD/E Learnings*** regarding the therapeutic use
- ***Rewarding RWE platforms for generating findings that inform treatment regimens*** by either direct financial support or through indirect mechanisms.



Two Key Differentiators of NEWDIGS Precision Reimbursement Approach

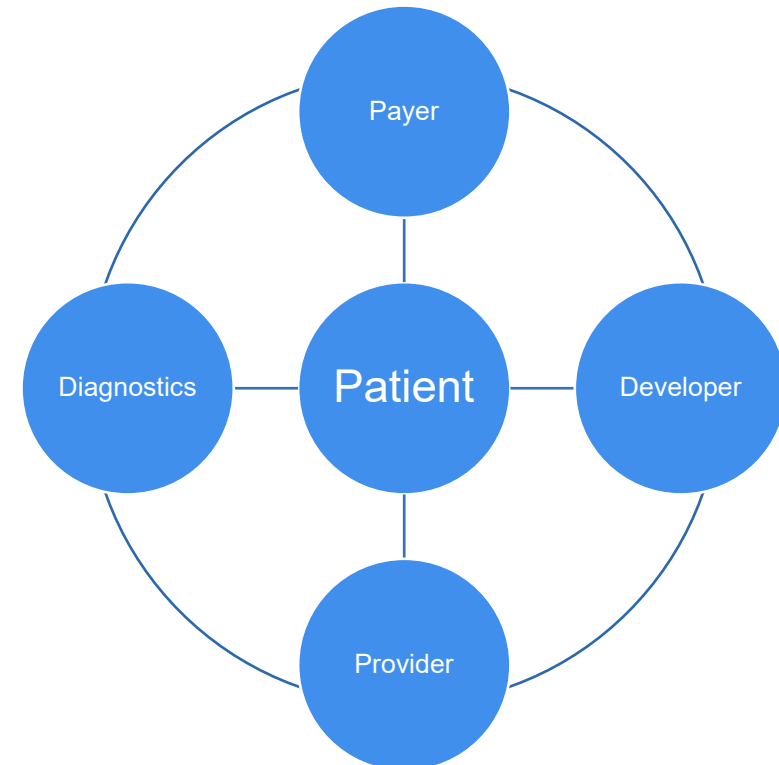
- **Align and connect incentives across all key stakeholders**
 - Providers, patients, drug distribution channels, biopharmas, & payers
 - Requires greater coordination in design and implementation WITHIN payer organizations
- **Continuous learning and improvement from RWE**
 - From enhancements in contract designs to discovery of new, clinically meaningful sub-populations to targeted regimen optimization
 - Requires improved outcomes tracking AND repurposing of outcomes data as one input into new RWE generation



Precision Reimbursement: Aligning Incentives to Achieve Patient-Centered Decisions & Outcomes

Precision Reimbursement Toolkit

- **Coverage & reimbursement designs**
 - *Value/outcomes-based contracts* (single or multi-party)
 - Flexible formularies (indication, regimen step & combinations)
 - Precision financing tools (FoCUS)
- **Risk-sharing agreements with providers**
- **Utilization management techniques**
- **Member benefit designs**
 - Co-pays
 - Co-insurance
 - Deductibles





Catalyzing Next Generation Payment Innovation To Enable Sustained Patient Access To Transformative Therapies



Jane F. Barlow, MD, MPH, MBA

Senior Advisor, FoCUS Project

CEO, Jane Barlow & Associates

EVP and Chief Clinical Officer, Real Endpoints

Next Generation Payment Innovation Roundtable

Discussion on payment innovation
across durable and chronic therapies



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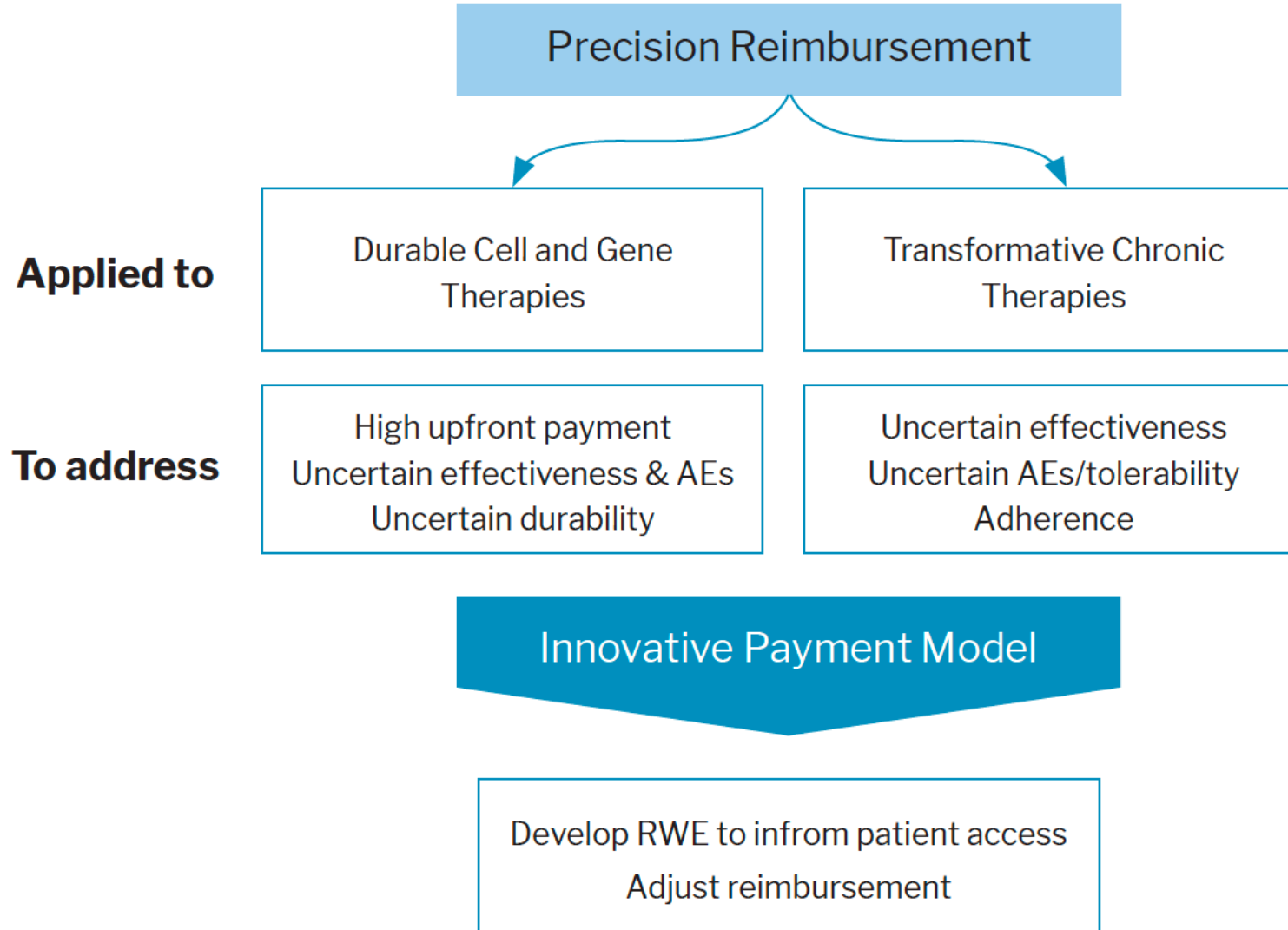
Goals of the Roundtable Discussion

- Examine and refine a framework of practical principles for payment innovation
- Identify critical needed capabilities and actions for implementation.
- Envision targeted multi-stakeholder collaboration to catalyze change.





Payment Innovation Application





Our View on Ideal Roles of Payment Innovation

Incentivize clinical use of therapies to

- Improve patient outcomes,
- Enhance healthcare system sustainability,
- Account for value created by upstream innovation.

Create scalable models with iterative learning cycles.

Contribute RWD/RWE regarding therapeutic use and outcomes.

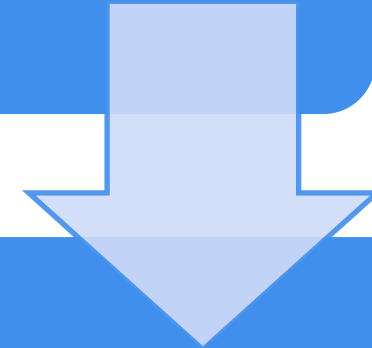
Reward RWD/RWE platforms for generating actionable findings.





A Payment Innovation Framework guided the discussion

- *Unmet needs*
- *Principles for payment innovation*
- *System changes to catalyze payment innovation*
- *Actions to catalyze change*



Participants included

- *9 pharmaceutical companies*
- *6 payers*
- *1 lawyer*
- *3 NEWDIGS*



Key Highlights

Desire to “educate the skeptics” within organizations

Lack of knowledge about payment innovation impedes systems change and uptake

Enable data sharing and Federated Learning

Value in sharing data in aggregate

Group interest in process learning and sharing best practices

Need for simple and specific solutions

Encourage accountability and flexibility by stakeholders

Interest in moving payment innovation towards larger disease populations

Type 2 Diabetes, cardiovascular disease, oncology



Potential Future Opportunities for NEWDIGS

Create a patient centric health framework for value-based contracting

Work with champions/change agents among our Consortia participating organizations to help understand payment innovation

Payment Innovation and Precision Reimbursement as its own initiative
Development of case studies and examples

Contribute to systems change in an efficient and sustainable manner



Next Steps for Next Generation Payment Innovation



- Publish proceedings to share refined framework
- Inspire individual action within your organizations
- Develop needed capabilities and actions through consortia



Discussion of Potential Actions

- Create functional standards for metrics and data collection
- Disseminate guiding principles for VBP engagement
- Develop Payment Innovation resources for persuasion and implementation
- Continue MDRP and other Federal policies to facilitate payment innovation

Future Precision Reimbursement Case Studies

Prioritization and Team Formation



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Precision Reimbursement Case Study Selection

Test generalizability of the framework - how do the archetypes fit into the framework

Look at different schemes across instances, are these schemes delivering the benefits anticipated going into the contracts. Provide evidence to skeptics that Prec Reim can work.

Process or Content/Tool Issue	Rationale	Case Study Nomination
Integrated design RWE learning and iteration	Potential high patient impact and system financial impact with uncertainties	Next generation weight loss products
Warranty (or outcomes-based agreement) effectiveness assessment	Patient isn't triggering the warranty, neither are providers	Bayer, Pfizer, and Takeda outcomes-based agreement/warranty
Behavior mismatch among urgency to presumptively treat vs waiting for Dx/staging information to arrive. (Ex. Cancer)	Resolve tension of action and knowledge. Really important for targeted therapies, connection to testing and total cost of patients (lifetime cost and outcomes of patient)	2nd round NSCLC? Some other cancer situation?
Small insurer /SIE pooling models for rare disease	Combine with FoCUS to advance	Synthetic enzyme replacement + others
Metformin for Gestational diabetes	Evidence exists but not widely implemented	Tufts Medical Center Ob/Gyn department
Patient access to Accelerated Approval medicines and/or small study rare disease therapies	Value uncertainty is leading payers to restrict, even exclude, coverage. Value-based contracts could address access AND evidence	Oncology case study. Perhaps rare disease



Case Studies Nominated to Date

1. Warranty (or outcomes-based agreement) effectiveness assessment: Next generation weight loss products
2. Behavior mismatch among urgency to presumptively treat vs waiting for Dx/staging information to arrive. (Ex. Cancer)
3. Individual small insurer & SIE cost burden for rare disease: Pooling models for enzyme replacement therapy round 2
4. Lack of commercial product incentives: Metformin for Gestational diabetes
5. Accelerated Approval evidence development: Using VBCs to generate evidence as well as access



Gestational Diabetes Potential LEAPS Case Study

- 10% of pregnant women develop gestational dm
- 50% higher incidence of Type II dm within 3 years
- 50% of those would not develop it if they received Metformin following their pregnancy
- Only 7% of those with gestational dm receive Metformin
- Multiple reason for this: payers won't pay (pt. mobility); mom's too busy with baby to deal with 2 weeks of side effects (bloating, diarrhea); I think they are then lost to follow up

<https://academic.oup.com/jcem/article/93/12/4774/2627340> (2008, 50% reduction)

<https://pubmed.ncbi.nlm.nih.gov/33860488/> (2018)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6243218/> (2020)



Rare Disease (traditional & durable) Pooling

- Problem statement:

Insurance works because the likelihood of something unfortunate happening to someone – the **risk** – is unpredictable, low and shared across a large pool

When a plan member has an inherited rare disease, the risk is predictable and often gets concentrated in families and plans

For one-time expenses like gene therapy or transplants, reinsurance often saves plans from being exposed to full costs

Majority of treatments approved for rare disease today are chronic and life-long

The model is not always sufficient especially for rare chronic treatments

- Current Status:

Precision financing solutions and proposals have been developed for durable cures, including the work done by Tufts NEWDIGS' FoCUS group

- Agenda:

Illustrate financial challenges/insurance issues with a synthetic disease

Discuss pooling solutions and implications

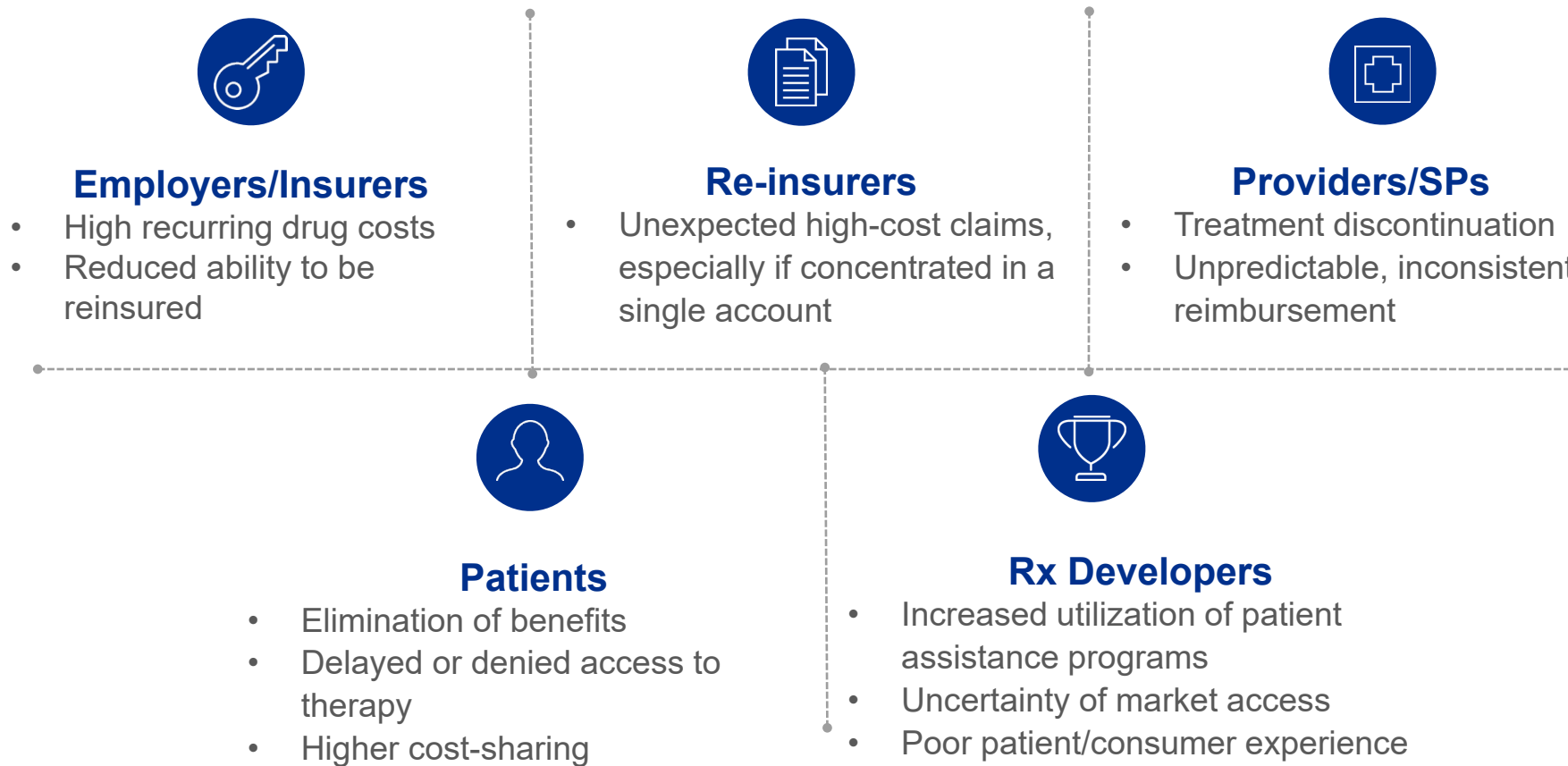


Financial challenges for a small self-funded plan





Stakeholder experience and challenges





Pooling approaches, tools, and scope

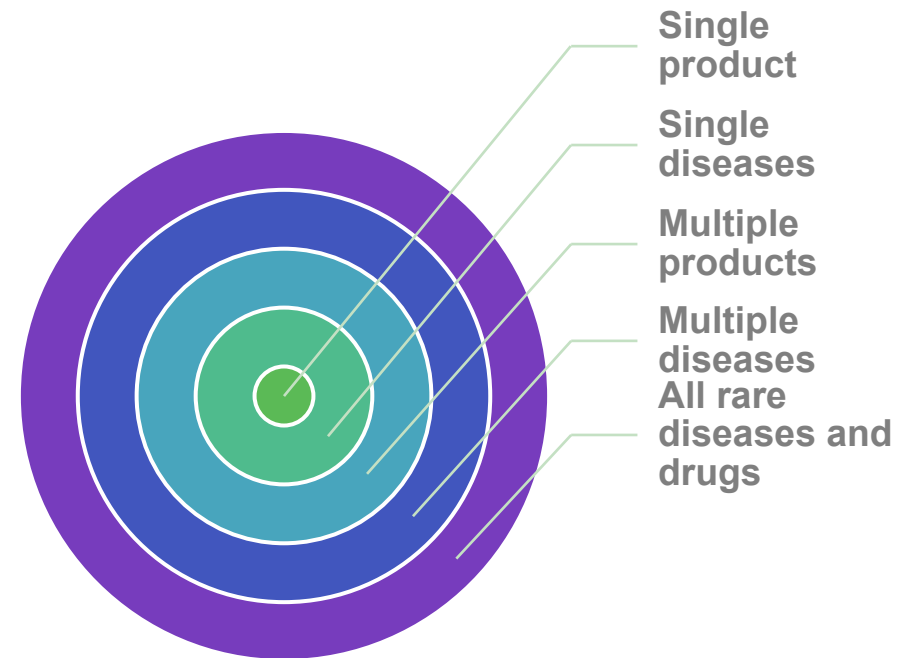
High Risk/Cost Patient Pools

- Pools to segregate and share high -cost patients with fixed annual payments by each payer
- Create a specific inclusion and exclusion criteria to pool funds

Type of pools

- **State run:** *State agencies may form a risk pool with a carve-out that may be used to pay for patient therapies*
- **National (private):** *Privately funded programs available for all rare diseases or only Zebra*
- **National (government):** *Federally administered and managed risk pool which combines the risk-bearing of reinsurers*

Scope of the Pool





The Design Lab today aims to understand opportunities and challenges with risk pools

Scope of the pool	<ul style="list-style-type: none">• Pooling approach and its features• Refine the pooling solution fit by stakeholder
Functional scope and implementation Issues	<ul style="list-style-type: none">• Financing, utilization management, contracting (drug only, medical), patient navigation and care coordination• Adverse selection and patient mobility issues• Enrollment and attestation process burdens• Adjudication and payment mechanisms• Sustainable funding mechanisms
Patient access perspective	<ul style="list-style-type: none">• Risk of delaying access through additional process burdens• Impact on patient out-of-pocket costs• Enrollment and attestation process burdens• Opportunities/challenges to connect with patient organizations and assistance funds• Benefit of facilitating out-of-region (and out-of-network) care at centers of excellence
Learning from curative/durable therapies	<ul style="list-style-type: none">• Shared issues for durable therapy use of pooling for SIEs



Five Breakout Groups

Pooling fit by stakeholder benefits and challenges:
SIEs/small insurers; providers; patients

Pooling fit by stakeholder benefits and challenges: **Stop Loss/reinsurers; specialty pharmacy; developers**

Durable therapy emphasis –
Explore shared issues for durable therapy use of pooling for SIEs/small insurers with pre-existing populations such as SCD, Hemophilia and perhaps oncology

Private pooling for SIEs Deep Dive: into design and operational considerations

Patient access perspective –
Pooling impact on out-of-pocket costs and administrative barriers



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Lipids Management Webinar and Community Creation

Prioritization and Team Formation



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Precision Reimbursement Lipids Mgmt Webinar

Goals:

- Share our learnings
- Catalyze a community of practice



LinkedIn promotional language

Join @NEWDIGS Initiative and @theFHFoundation for a virtual Learning Session on **Wednesday, December 7th: Improving Cardiovascular Outcomes Using Precision Reimbursement**

This collaborative learning session will examine the persistent challenges and significant gaps we face in achieving optimal lipid management outcomes for patients to reduce #cardiovascular events and improve patient and population health.

In this 1-hour session, we will:

- **Examine** the current state of lipid management for ASCVD and other high-risk patients
- **Explore** how Precision Reimbursement strategies and tools could incentivize all stakeholder groups to work together to improve outcomes
- **Discuss** how some of these innovative methods are being implemented by organizations in the NEWDIGS Initiative's collaborator community