CHEAT SHEET

for Health plans and payers

Data intermediation in performance-based drug agreements

Preparing for multi-stakeholder data coordination around patient clinical outcomes

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Key takeaways

- In order to have a successful performance-based agreement (PBA), data needs to be collected throughout the patient journey and shared across multiple stakeholders.
- The current ecosystem is not conducive to collecting and sharing data across partners, especially after a patient leaves a plan.
- New solutions will need to address milestone determination and patient mobility in order to make progress in the ultra high-cost drug space.

What is it?

Data intermediation consists of the collection, storage, dissemination, and analysis of data gathered around patient outcomes for the purpose of determining if performance-based agreement milestones have been reached in the time stipulated in the contract.

There are four major moments in the data intermediation workflow:

1. **Collection**– *Who is collecting the data and what data is being collected?*
   The first component is what data will be used as a metric to determine drug performance. After milestones are established in the PBA, data is then collected around these (typically clinical) milestones by providers after the treatment is administered. However, non-diagnostic visit patient data may be collected to determine the efficacy of the treatments as well, if available.

2. **Storage**—*How is the data being stored so that it is auditable if required?*
   The drug performance data will need to be stored in such a way that it is open and accessible to the contracting stakeholders. There are many restrictions on what elements of the data intermediation infrastructure manufacturers can directly support, due to federal regulations like the Anti-Kickback Statute. For this reason, diagnostic tools and storage are often paid for, and operated by, a third party, health plan, or a state 'data aggregator'.

3. **Dissemination**—*How is the data flow being directed to the appropriate parties?*
   The collected data must appropriately flow from providers, to storage, to both manufacturer and purchaser. For ultra high-cost drugs this dataflow could occur anytime a patient interacts with the health care system.

4. **Analysis**—*How are the results of the data collection used?*
   The data needs to be processed so that there is agreement between the contracting parties on whether the therapeutic milestones (as described in the PBA) were achieved so appropriate payments can be made between the contracting parties.

1. Inpatient care management relies more heavily on RNs and social workers to staff their programs.

Source: "What is a Cancer Registry?," NIH, https://seer.cancer.gov/registries/cancer_registry/data_collection.html
Advisory Board interviews and analysis.

Why does it matter?

Latest pipeline forecasts indicate that about 60 durable therapies will enter the US market by 2030. This will pose a serious financial challenge to the stakeholders eager to provide patients with these life changing medications. Many of the creative contracting solutions that will help mitigate against the financial, and performative, risks associated with these novel therapies (such as performance-based arrangements) will require a robust data infrastructure to adjudicate patients' therapeutic outcomes.

PBAs continue to be one of the more intriguing approaches to increasing accessibility to these ultra high-cost drugs (UHCDs), but they require new forms of operational coordination between healthcare stakeholders. One of the most important of these is the organization of the flow of data around patient therapeutic outcomes---'data intermediation'. Our literature reviews and conversations with experts have clearly indicated that 1) this is likely the most difficult aspect of stakeholder coordination around ultra high-cost drugs 2) there is a lack of understanding among the vast majority of stakeholders about how challenging data tracking will be 3) few organizations have attempted to develop a data infrastructure that is necessary to adequately track and share therapeutic outcomes for ultra high-cost drugs.

Tracking therapeutic outcomes for these novel therapies is especially difficult because of the shortcomings in interoperability among Electronic Health Record (EHR) platforms. Advancement in these platforms would provide a useful first step towards a more continuous flow of real-world data for contracting entities.

Despite the many roadblocks, the proliferation of gene and cell therapies will require payers to work with other stakeholders to share and utilize data more efficiently to encourage affordable access to these life altering treatments.

Source: Paying for Cures Toolkit, MIT,2021, https://payingforcures.mit.edu/patient-assessment/.

How does it work?

In practice, it is the flow of data *through* the four data intermediation moments that enables a performance-based arrangement to work. Data needs to be collected, stored, disseminated, and analyzed throughout the ultra high-cost drug's journey from the contracting moment to its performance evaluation.

The data intermediation component of stakeholder coordination around UHCDs is the most difficult for two reasons – it can be very challenging to collect (and correlate) UHCD patient data beyond the data coming from the diagnostic visits, and it is even more challenging to do so if the patient changes plans or providers during the time period stipulated in the payment agreement. The ability of the original contracting payer to access the UHCD patient's data from the latter's new healthcare system has proven to be the most intractable of all the stakeholder coordination issues in PBAs to date.

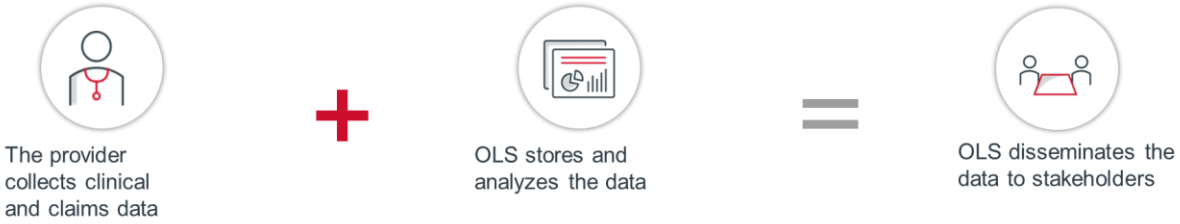
An example of this process in practice is the Spark Therapeutics outcomes-based arrangement for Luxturna, a therapy that treats Leber Congenital Amaurosis in children. Their agreement includes a provision which stipulates that Spark shares the risk with certain health insurers by paying rebates if patient outcomes fail to meet a specified threshold, both in the short term (30-90 days) and long term (30 months). Both measures will be based on full-field light sensitivity threshold (FST) testing scores that are compared to pre-treatment baseline scores. In this case, the center of excellence provider that Spark contracts with collects and stores the outcomes data, and then the manufacturer (Spark) disseminates that data to the other stakeholders for analysis.

Data flow in Spark's Luxturna outcomes-based contract

Source: Sagonowsky, E, "Spark, Novartis tie up in gene therapy licensing deal worth up to $170M" FiercePharma, January 2019; Spark Therapeutics Announces First-of-their-kind Programs to Improve Patient Access to LUXTURNA™ (voretigene neparvovec-rzyl), a One-time Gene Therapy Treatment", Spark Therapeutics, January 2018; Advisory Board interviews and analysis.

Optum Life Sciences (OLS) represents a different stakeholder configuration around these four moments of data intermediation. OLS leverages their relationship with Optum Payer Analytics, which covers 68% of commercial lives and 57% of Medicaid lives, to track UHCD patients' clinical and claims-based data across multiple healthcare systems and then shares that data with the contracting stakeholders. In this scenario, the provider operates as the data collector (both clinical and claims), while OLS operates as the data correlator, storer, and disseminator to the contracting stakeholders.

Data flow in Optum Life Sciences Arrangement



There are several other data gathering solutions currently on the market, with different stakeholder configurations around the four data intermediation moments (pg.10). However, These different stakeholder configurations generate both data tracking opportunities and unique constraints on that capacity. Spark's approach eliminates the challenge of patient mobility between plans but at the cost of forcing patients to repeatedly travel to one of their designated Centers of Excellence. On the other hand, OLS allows for much more provider flexibility for patients but at the cost of patients potentially leaving OLS's pre-existing data gathering network.

While the market has responded to the need for more robust data gathering services for UHCD patients, these solutions will need to continue to innovate in order to meet the challenge from increasing numbers of UHCDs and PBAs.

Source: "Health plan solutions," Optum, https://www.optum.com/business/solutions/health-plans.html; Advisory Board interviews and analysis

Summary of current market solutions by MIT's NEWDIGS FoCUS consortium

Company	Data source
Audaire Health *Gene & Cell Therapy Outcomes Management Service*	Providers
August Care *Outcomes-based Financial Solutions*	De-identified patient data from integrated sources
BCS Financial *Stop-loss Gene Therapy*	Self insured medical and pharmacy administrators
BlueCross Blue Shield Association *Blue Distinction Center for Cellular Immunotherapy*	COE, providers
CVS Health *Gene Therapy Stop Loss,* *Gene Therapy Payment Plan*	N/A
Emerging Therapy Solutions *ETS Programs of Excellence, ETS Analytics & ETS Buyers Group*	Variable, based on consumer needs
OptumRX *Optum Gene Therapy Risk Protection*	Varies by condition and/or therapy including patient surveys, medical claims and pharmacy claims
OutcomeRX *Specialty Therapy Warranty*	Payers or providers, based on warranty structure
PayRX *PayRx Benefit Protection*	Payers and payer requirements
Real Endpoints *RE Marketplace*	Payer pharmacy and medical claims

Source: "Emerging market solutions for financing and reimbursement of durable cell and gene therapies", FoCUS, June 2021.

Conversations you should be having

01 The data points your organization believes are most important to assess therapeutic performance

02 Your organization's ability to collect a patient's clinical data, especially across other plans/provider networks

03 Your organization's familiarity with 3rd party clinical data tracking products

04 How contracting parties will encourage patients to continue to check-in after the treatment has been administered

Two areas within this process pose the greatest challenge to creating a successful data infrastructure and are where you should consider positioning your resources.

Milestone determination: Manufacturers have pushed for milestone criteria that align as closely as possible with the clinical trial environment, because of the lack of real-world evidence for most of these therapies. Purchasers have attempted to add more flexibility to those criteria to broaden these agreements to cover as many members, in as many circumstances, as possible.

Data tracking: Stakeholders have expressed how important it is to be able to track and correlate not only data from the diagnostic visits that determine milestone achievement, but from the patient's medical journey more generally in order to assess the efficacy of the product. Collecting these patient data streams across other healthcare groups poses a very serious challenge to small and mid-sized payers.

Source: Advisory Board Interviews and Analysis

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