Aligning performance based contracts for drugs and healthcare delivery – US and EU perspectives

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There are common drivers that favour a move towards an integrated, outcomes oriented health ecosystem...

- **Better understanding of disease** leading to smaller patient populations
  - Advances in science and the targeting of disease, to define more focused patient groups
  - Increased costs per treatment within these groups
  - Multi-indication drugs with differential value across indications

- **Faster Regulatory Pathways** leading to smaller evidence packages at launch
  - More post-launch studies and commitments
  - Greater clinical uncertainty at launch

- **Value-Based Provider Reimbursement and HCP Compensation**
  - Performance metrics, linked to reimbursement rates
  - Payment by results and risk-sharing
  - Primary care gatekeepers

- **Affordability Concerns**
  - Demographics
  - Expanding universe of targets, mechanisms of action, combinations
  - Cost density of curative therapies
This is often expressed by health systems as value-based care.
Even in the U.S.’s convoluted systems, the connection between quality and outcomes is an every day reality.

Inpatient
- **FFS**
  - **MS-DRG**
    - Lump payment per case set by average resource utilization with global rates tied to quality metrics

Pharmacy
- **Open Formulary**
  - **Closed Formulary**
    - **Value-Based Contract**
      - Reimbursement and net price tied to measured real-world outcomes

Outpatient Medical
- **Medicare**
  - **FFS**
    - **ACA**
      - **FFS**
        - **ACO**
          - **MACRA**
            - **MIPS**
              - **Adv. APM**
                - **Preferred Vendors**
                  - FFS rate tied to data & quality metrics
                  - Assume up/downside risk, for bonus and higher rates

**MCOs**
- **FFS**
  - **ACO**

**IDNs**
- **Payer/Provider**
  - Direct control over staff HCPs to control costs

**Glossary**
- **FFS**: Fee-for-service
- **ACA**: Affordable Care Act of 2010
- **MACRA**: Medicare Access and CHIP Reauthorization Act of 2015
- **MIPS**: Merit-based Incentive Payment System
- **Adv. APM**: Advanced Alternative Payment Models

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Thus, Value-Based Contracts (VBCs) are increasingly being considered to support market access to innovative therapies.

1. *Identifies a set of mutually-recognized outcomes* that reflects the clinical or economic benefits provided by the product for defined use in a specified patient population.

2. *Specifies the measurement of these outcomes in real-world populations* and defines the data sources, processes, and threshold that separate “good” from “poor” outcomes.

3. *Defines a formula and payment terms that link the net price or reimbursement to these measured outcomes*, with contract terms that include provisions for auditing and adjudication.

**Recent VBC examples**
- PCSK9s, HCV
- Pay by results (Italy) and market access agreements (UK) in oncology, immunology, rare diseases
Huron/PW recently conducted primary research with US and EU payers in the area of VBCs to assess the future environment.

**Past**
- Limited Alignment on Proxies for LT Outcome
- Inconsistent → Poor Data Capture
- Disconnect Between Any Existing Metric & Physician Behaviours

**Focus**

**Objectives:**
- Capture latest trends and outlook
- Understand ‘real-world’ motivations to enter (or not) VBCs
- Identify hurdles and potential solutions
- Create a basis for actionable guidance to pharma

**Approach:**
- US: 12 medical or pharmacy directors of MCOs, PBMs and IDNs
- EU: payers in Italy (n=7), UK (n=6), France (n=1), Netherlands (n=1), Sweden (n=1) and Poland (n=1)
Value based contracting feasibility is increasing in line with trends in drug and technology development

<table>
<thead>
<tr>
<th>Drug/Device Specific</th>
<th>Payer Specific</th>
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<tbody>
<tr>
<td>• Clinically-relevant outcomes exist to measure RW performance within ~3y</td>
<td>• Ever increasing IT capabilities enable adjudication</td>
</tr>
<tr>
<td>• Budget impact is significant to warrant the additional effort</td>
<td>• Expected benefit warrant effort, relative to other activities</td>
</tr>
<tr>
<td>• Multiple indications create a clear rationale to consider different outcomes differently</td>
<td>• Contracting window is open when substitutes, level of unmet need, and trial data allow restriction</td>
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<table>
<thead>
<tr>
<th>Disease Area</th>
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<tbody>
<tr>
<td>• Smaller targeted populations with more homogenous patterns, often w/CDx</td>
</tr>
<tr>
<td>• Highly novel technologies enabling transformational outcomes</td>
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<tr>
<td>• Data collection is increasingly required as a baseline within gold standard clinical pathways</td>
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Current attempts a value-based contracting have often been treated as a “bolt-on”, further complicating an already complex ecosystem.

- **Negotiate Base Rebate**: Negotiate preferred access, giving drug “benefit of doubt”
- **Set At-Risk Rebate**: Define added rebate if RWE fails vs. base assumptions
- **Measure & Execute for Patient Cohorts**: At-risk rebates triggered based on cohort performance

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**Providers**
- Deep (with labs) but requires data link to providers
- EMR Data
- Medical Claims
  - Visible to holders of medical risk, but limited in depth
  - Easiest source to measure VBC outcomes (universal visibility, same budget item as drug)

**Payers**
- IDN
- MCO
- PBM

**Medical**
- 3rd Party
  - Payers’ data used to measure outcomes; manufacturer may pay for audit

**Pharmacy**
- Pharmacy claims
  - Adherence
  - Terms limited to adherent patients

**Pharmacies**

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**Manufacturers**

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Value based contracts in the U.S. today are an evolution, not a revolution, in access negotiation, but this evolutionary nature facilitates wider adoption

**Value Based Contracts Today**

- Driven by transfer of risk from payers to manufacturers, and MCOs’ marketing to plan sponsors as being innovative in “bending the cost curve”
- Terms mainly guarantee real world performance matches trial data, per label
- Outcomes employed are restricted by data availability, making most current contracts relatively simple (e.g., adherence-based)
- Simplicity of design supports broad use, tacked onto rebate structure needed to gain preferred formulary access

**Implications for manufacturers**

1. **Trials still matter!** VBCs won’t rescue access for a premium-priced drug if the trial data are poor, or if the trial comparator/population is irrelevant
2. Payer negotiations remain governed by gaining formulary access, with VBCs adding an extra HEOR-informed stage if seeking preferred formulary position
3. Distorted incentives from split medical/pharmacy risk remain, and may worsen as payers shift medical risk onto providers
EU payers cautiously predict some growth of VBCs

• In recent past, not much acceleration of the historical trend in EU VBCs
  • pay by results schemes in Italy ‘keep going’
  • a handful of market access agreements with NHS England

• Yet, all cautiously agreed VBCs make sense and will grow within 2-5 years
  • cell/gene therapies (accelerated regulatory pathways)
  • legislative changes and EU-level partnership initiatives
  • improvements in RW data capture and integration
  • a simple financial component will likely be associated
## Payers high-level objectives (public mandate) frame the incentives/metrics for VBCs

<table>
<thead>
<tr>
<th>Performance metrics/ incentives</th>
<th>UK</th>
<th>Italy</th>
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<tbody>
<tr>
<td><strong>Financial sustainability</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Reduce budget impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Manage financial risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Accelerate access to innovation</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Support the right clinical and value for money decision</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>- Mitigate uncertainty on response/outcome</td>
<td></td>
<td></td>
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<tr>
<td>- Support appropriate use (start and stopping rules)</td>
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<td></td>
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<tr>
<td>- Learn and re-assess based on RWE (still a theoretical argument)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ensure smooth, efficient running of HC system</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Avoidance of admin burden</td>
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The research surfaced less publicised, yet substantial hurdles for VBC

- Payers strongly emphasised the ‘political’ and ‘negotiation’ factors
  - sense of antagonism and distrust between pharma and payers; negotiations are suboptimal
  - multi-stakeholder partnerships, e.g. with providers and ‘honest brokers’ (HTA body?) can help

- True involvement of physicians in VBC design and buy in, is key to make VBC work
  (data collection)

- Payers perceive pharma is getting better at making meaningful and timely proposals, but preparedness for VBC negotiation should be improved
  - upskill both sides (payers and pharma)
  - upfront emphasis on simple design and contracts generating low admin burden
In summary we have identified some KSFs

- **Clear and present need**
  - therapy addresses real unmet need
  - health/financial benefits are promising but uncertain
  - budget impact of the therapy is large

- **Real cost savings must ultimately be enabled**
  - Incentives for payers to enter a VBC are part of, or overlaid on, the basic framework of payer metrics
  - Must be considered holistically rather than as a ‘fix’ or ‘patch’ opportunistically employed by payers on top of traditional volume based agreements

- **Ability to capture the chosen outcome easily and within a short timeframe**
  - Legally enabled
  - Technically feasible
  - Low cost/low burden

- **True trilateral (manufacturer, payer, provider) alignment**
  - In the US this may well mean large IDNs are the ‘low hanging fruit’
Who will lead the way in a multi-stakeholder, data-driven partnership: pharma, IDNs, ...or Google?

Trilateral models are highly challenging, but IDNs may lead the way

- **Payers**: Sharing of medical risk, incenting providers to reduce medical cost while hitting quality targets.
- **Pharma**: Tying pricing to real-world performance via value-based contracts, primarily under the pharmacy benefit.
- **Providers**: Contracting under the medical benefit.
- **Messaging & services to incent providers to adopt drugs, reflecting evolving incentives.**

US example
Will VBCs and supporting data partnerships lead to a more sustainable, learning health care system?

Real impact on decision-making
• uncertainty reduced for the outcomes that were the focus of the scheme
• successful process that underpinned a decision with further evidence

Verified quality and efficiency of execution
• integrity of the design maintained
• governance arrangements worked well
• the scheme run to budget and time

Data integration and analytics
Use in optimally designed VBCs
Learning, re-assessment, better decisions

What should happen…but is not a reality yet ¹

### Call for action for pharma – be in the driving seat with VBCs

#### What do you think?

<table>
<thead>
<tr>
<th>Question</th>
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<tbody>
<tr>
<td>How can Pharma help align the stakeholders on performance metrics?</td>
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<td>How can Pharma ensure physicians are engaged?</td>
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<tr>
<td>What data/IT initiatives would you lead, join or support?</td>
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<tr>
<td>What capabilities need to be developed.....do they belong to Pharma today or other “non-traditional” players?</td>
</tr>
</tbody>
</table>
Appendix
Who will drive transformation?

**Companies with >$1B in WW anti-diabetic revenues (2016)**

- Deeper rebates competing for favorable formulary position(s)
- Value-based contracting as “price of entry”
- Reduced willingness to pay for therapeutic improvements
  - “The incremental improvements [among insulins] don’t seem to justify the premium prices.” – Express Scripts CMO

**Device**

- “Artificial pancreas”, with diagnostic feedback governing insulin metering
- Novel glucose monitoring (e.g., implantable wire connected to app)