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Strategic & Operational Requirements For Value-based Contracting: Panel Discussion Content

Novel Contracting Approaches

Non-Traditional Pricing / Contracting Can Take Two Fundamentally Different Forms

Financial Based (conditional payment)

- Cost and / or utilization limits are placed on products / indications, beyond which no reimbursement is provided
  - Number of patients on therapy
  - Global spending cap
  - Number of doses per treatment course per patient

Performance Based

- Price / reimbursement tied to future measures of clinical endpoints / medical services utilization (drug efficacy, disease markers, endpoints, avoidance of AEs avoidance of interventions / utilization)
- Contractual levers can include treatment initiation funding, contingent rebate, reimbursement cut-off, etc., in exchange for preferred positioning
- Agreements can be at brand, portfolio or TA (product agnostic) level
- Competitive pilot “trials” whereby brands are given temporary preferred positioning as comparable effectiveness is evaluated and preferred drug is determined

Ex-US Examples

Financial Based Contracting Efforts Have Not Been Uncommon in UK

Sponsor	Drug	Counterparty	Year	Description
Biogen Idec	Avonex	UK	2002	Maximum price/QALY of £36,000. If cost-effectiveness target not met, Biogen refunds payer.
J&J	Velcade	UK	2007	Reimbursement to payers for patients who don't respond after 4 cycles (each cycle $6000)
Bayer	Levitra	DENMARK	2005	Refunds to unsatisfied patients
J&J	Velcade	UK	2007	Reimbursement to payers for patients who don't respond after 4 cycles (each cycle $6000)
Novartis	Lucentis	UK	2008	Novartis pays for all treatments beyond initial 14
Celgene	Revlimid	UK	2009	Celgene pays for anything beyond 26 cycles of the drug
GSK	Votrient	UK	2010	12.5% price cut and undisclosed rebate if fail to succeed in head to head trial against Pfizer's Sutent

US "Legacy" Case Studies

The Number Of Visible, Successful Contracting Efforts In The US Have Been Limited

	Company (year)	Health Plan	Agreement	Results
Januvia (sitagliptin) tablets	Merck (2009)	CIGNA	Preferential formulary placement in return for discounts for any compliant patient taking *any* OAD drug	~5% improvement in compliance and blood sugar level after 1 year
Actonel (risedronate sodium) tablets	P&G / Sanofi (2009)	Health Alliance	Plan is reimbursed for any non-spinal fracture suffered by an Actonel patient (capped)	Fracture events consistent with trial data; Payments to plan 79% of cap
oncotype DX Breast Cancer Assay	Genomic Health (2009)	UHC	Plan reimburses list price for 18 mos; discount applied if patient is still on chemo despite support test result	N/A
Rebif (interferon beta-1a) sc injection	EMD Serono (2012)	Prime Therapeutics (BCBS PBM)	Favorable reimbursement terms for adherence rates, as well as relative total cost-of-care measurement	N/A

Recent Developments

Indicators of Shift to Value Contracting

Eli Lilly and Company and Anthem:

•Joint perspective on creating legislative and regulatory options designed to promote value-based contracting arrangements for manufacturers and commercial plans

- POLICY GOAL: Create a policy environment conducive to allowing health plans and manufacturers to enter into a variety of value-based contracting arrangements, aligned with the shift toward value-based payment and the goal of promoting access to high-value care. This may include creation of legislative/regulatory exceptions for Best Price and all other relevant government pricing calculations and requirements

Novartis Heart Failure:

•In clinical trials they showed that Entresto significantly reduced the rate of hospitalization for heart failure. So their deal with Cigna & Aetna is to offer a modest base rebate on the drug, which will then either rise or fall based on how successful they are at reducing the rate of hospitalization.

Amgen - HCHP

•Amgen negotiated a P4P deal with Harvard Pilgrim for its cholesterol drug Repatha (PCSK9 inhibitor) wherein there is an upfront discount offered, with potential further rebates if the drug does not help patients hit target cholesterol levels. Combined with volume based discounts.

HCV "Pay For Cure"

• 98-99% cure rates. Payers only pay for the treatment courses that successfully result in a cure. So they pharma company is effectively guaranteeing a cure.

Underlying Drivers of VBC

- Drivers:
  - *Providers / Professional:* RWE initiatives; value frameworks (ASCO, MSK, Mayo); Oncology (NCCN – evidence blocks, ICER, ASCO, Abacus)
  - *Payers:* more & more aggressive, even for game changing meds (HCV)
  - *Public:* Spotlight is being shined on pharma due to pricing practices; increased scrutiny

  Spillover to politics & legislation
  - Legislation (Innovation Bill and Rx Drug User Fee Act) with potential to increase role of RW

Underlying Drivers of VBC

Mkt Trend	Drivers

Increased Scrutiny on Drug Costs	• Threat to buy and bill model, evidenced by:
	  • Policies and programs to drive value based purchasing, reduce pricing margin (CMS Demonstration Project, Express Scripts Oncology Program).
	  • Increased payor consolidation → bargaining power
	• Continued expansion of 340B
	• Repeal of non-interference clause (Medicare Part D) for sole-source drugs
	• Increasing focus on value-based measures (described below)
	• Potential for biosimilars

Increased Focus on Value-Based Care/RWE	• Increasing influence of quality based medicine • Increasing role of patient advocacy groups • Introduction of value framework assessments (e.g. ICER, ASCO, NCCN) and implementation bodies • Legislation (Innovation Bill and Rx Drug User Fee Act) with potential to increase role of RWE
Policy Reform: MACRA: APMs / MIPS; Others	• Increasing focus on care pathways and value-based measures • Focus on reducing cost of care (inclusive but not limited to cost of drug)
Growing Influence of Care Pathways	• Increasing payor management of oncology (i.e. beyond traditionally managed indications) • Pressure on providers to adjust practice patterns based on payor management, APMs, etc.

Product Requirements

Outcomes Contracting Has Been Considered In Certain Pharmaceutical Market Segments

Characteristics of products / indications appropriate for outcomes contacting

- Clearly identified population
- Clearly defined metrics / outcomes
- Monotherapy patient management
- Straightforward measurement
- Provider ability / willingness to manage patient protocols
- Products having uncertain efficacy and / or treatment duration
- High budget impact (high priced drugs in smaller indications)
- Modest differentiation / limited unmet need

Examples

Diseases of Interest

- RA
- MS
- Oncology
- HAE
- Sickle cell
- Orphan
- Diabetes
- HCV

Drug Classes of Interest

- Anti-TNF
- Immune modulators (e.g. interferons, mAbs)
- Hormonal agents
- Anticoagulants
- OADs

Barriers To Adoption

Pharma Outcomes Contracting In The US Faces Distinct Challenges

Structural Barriers

- Payer fragmentation (separate negotiation requirements)
- Limited provider integration (relative to EU)
- Health plan membership churn (particularly outside of large, regionally dominant systems)
- Increasing use of polypharmacy in many disease states
- Effectiveness of internal customer disease mgmt in some diseases

Operational Barriers

- Patient identification, metric definition agreement
- Siloed pharmacy and medical benefits
- Lack of customer / data source readiness
- Lack up alignment on contractual incentives (e.g. customer desire for upfront vs. downstream economic rationale)
- Need to reconcile with existing rebate-oriented contracts
- Solution implementation complexity; resource requirements
- Anti-kickback statutes and govt pricing….

Marketplace Implications

Interest Exists, But True Outcomes Contracting Remains Relatively Limited Today

Anti-Kickback Statutes: Federal and state fraud and abuse laws are designed to protect patients, health plans, and the healthcare system overall from fraud, waste, and abuse. The Anti-Kickback Statute (AKS**) prohibits offering or receiving remuneration (broadly defined) to induce or reward referrals** for items or services paid for by federal healthcare programs. **Statutory and regulatory safe harbors protect certain arrangements** from AKS liability, but it is **unclear how enforcement agencies would apply these safe harbors to value-based arrangements.** AKS violations carry significant financial and other penalties.

Government pricing: Manufacturers are required to report pricing data to the federal government to determine Medicaid rebates; Medicare Part B payment rates; the 340B program ceiling price; and the maximum price that certain government agencies can be charged. Because these reporting requirements did not foresee and were not designed to be compatible with value-based contracting, they **could make it exceptionally difficult for a manufacturer to enter into a value-based contract**. For example, current Medicaid rebate regulations would require that rebates paid to a commercial health plan in the context of a single value based contract be made available to Medicaid programs, even though Medicaid programs would not be subject to the key design features of the value-based arrangement

Med Tech Considerations

Barriers Are Particularly High In Medical Device & Diagnostics

Clinical Rationale

- *Limited added benefit*
  - For medical devices, improvements vs. existing options are often incremental, making it difficult to prove/disprove that a better outcome has been achieved
  - Additionally, pre-market efficacy data not normally collected
  - Technique-dependent implantation can be another factor

Outcomes Heterogeneity

- *Multiple contributing factors*
  - Devices (and diagnostics) are often only one component among multiple modalities that lead to a measureable endpoint, making it difficult to assess their specific contribution to a given outcome
  - Adherence not often a factor in driving outcomes

Timing of Impact

- *Temporal & procedural distance from outcome*
  - Potentially long (and increasing) device durability and length of time until an outcome (positive or negative) can be confirmed