Can outcomes-based agreements support appropriate, affordable and accessible health care?  
Payer Perspective

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Disclosure

- I am employed by Alberta Health (Government of Alberta)
- Past life: Consultant (Government and Industry) & Pharmaceutical Company
OBA
Potential Benefits

• Contracts could prevent payers from paying for expensive drugs that may not be as effective outside of clinical trials.
• Contracts could provide an alternative to closed formularies, allowing a drug to remain on a formulary in exchange for outcomes guarantees:
  – Manufacturer retains sales volumes.
  – Payer and manufacturer share financial risk if drug does not meet target outcome.
  – Patients provided coverage.

Seeley et al., Commonwealth Fund 2017
IN THE NEWS

• Considering the Side Effects of Drugmakers’ Money-Back Guarantees\(^1\)
  – scant evidence this new approach lowers costs
  – “..get launched with great fanfare,”
    • “But then you never hear anything about it after the launch because most of them collapse under their own weight.”

• Value-based pricing vs. outcomes-based contracting\(^2\)
  – Is the price correct in the first place?

1. Thomas et al, *The Times and ProPublica* 2017
2. Kaltenboeck et al., Drug Pricing Lab 2017
IN THE NEWS

• Refunds unsuccessful in improving cost-effectiveness of PCSK9 inhibitors\(^1\)
  - “One may accept the tenuous premise that, if a patient had a heart attack, [the drug] did not work” “Thus should not pay for it.”
  - However, it does not mean that, if a patient did not have a heart attack, the agent did work and thus should pay for it.

• Money-Back Guarantee’s for Expensive Drugs: Wolf’s Clothing but a Sheep Unerneath\(^2\)
  - Under OBA, \(\sim 3\%\) improvement in CE
  - Prices could be much higher under OBA then if the price was based upon value.
  - Why an insured enter into a OBA is mysterious.

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Challenges
Outcomes Analysis

• Which outcomes will be tracked
  – For how long?

• Definitions of treatment success

• Data collection
  – New (who to collect) vs already captured

• Analysis
  – analytical methods, such as adjustment for confounders and relevant covariates
  – Patient movement
OBA
Not a replacement for HTA

• Mitigate implementation for:
  – Drugs which have not been appraised, to list before completing appraisal, or have been appraised but not recommended.

• Case Study: UK Cancer Drugs Fund
  • Established in 2010 to improve access to cancer drugs, including some appraised but not approved by NICE
  • 29 cancer drugs funded for 47 indications at Jan 2015 (£50M initial budget 2014, £340m 2015/2016).
  • Six years and significant expenditure later: reverting to a system including independent health technology assessment

“The lack of empirical evidence that prioritizing drug expenditure (the greatest cancer care costs after inpatient care) will improve outcomes for cancer patients over and above greater investment in the whole cancer management pathway (screening, diagnostics, radiotherapy, surgery) and reducing access barriers (e.g. co-payments) argue against its widespread adoption.”
“If You Could Read My Mind”

Financial Risk

Unfavorable Outcomes and Active Disinvestment

Concept to Complex Methodology

Capacity / Support

Case Example

– Confidentially Provisions
– Solid clinical treatment pathway
  • Non-inferior RTC relative to the current standard of care.
– Industry assumes the financial risk from the start
  • No retroactive financial risk to the payer
  • Payer mitigated to be put in a position to delist or implement restrictive criteria if new evidence demonstrated poorer CE or failure of OBA
– Agreement in principle easy to reach
  • Small ‘leap of faith’ needed
  • Details on methodology and thresholds can be protracted
– Strong role of third party – e.g. academic group
  • Understanding of ‘imperfections’ of existing data, no new data or inter-provincial data needed. Academic strong ties to clinicians
Challenge as a Payer

Need for OBA approach?

Desire for OBA

Price for value too high with OBA

Adjust price on value

Other Factors:
- Me-too drug?
- No clinical or cost benefit over comparators?
Considerations

- Not all drugs are good candidates for an OBA
- May still require substantially discounted baseline price
  - Allows for a broader definition of value while improving sustainable drug access
- Outcomes - meaningful and measurable
  - Implications of unmet outcomes
- Infrastructure / Expertise
- Cost/ability to pragmatically implement
Other Critical Success Factors

• Integrated into HTA, pCPA and local payer processes
• Willingness for proxy cohort:
  – Especially if not pragmatic to collect across P/Ts
  – Mitigate costly/resource intensive implementation
• Focus on meaningful, measurable outcomes
• Co-stewardship approach to agreements and disinvestment