

INNOVATIVE PAYMENT ARRANGEMENTS 101: OUTCOMES-BASED ARRANGEMENTS

What are OBAs:

Also known as value-based purchasing agreements (VBAs), OBAs are contracts between payers and biopharmaceutical manufacturers in which the manufacturer is reimbursed based on their product's performance and the patient's clinical outcome(s).

- Given the complexities of OBAs, initially, they could be implemented for gene therapies for rare disorders.

How do they work (generally):

1. **Contract:** Clear definition of terms and setting of goals for patient populations
 2. **Reporting:** Establishment of how data will be collected and managed
 3. **Data Analysis:** Calculations based on reported data to provide accurate reimbursement
 4. **Payment:** Reimbursement linked to terms based on agreed upon patient outcome(s), which may differ between contracts
- **Also to note-** Some stakeholders may be interested in a hybrid model where payment-over-time is combined with OBAs

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- Outcomes-Based Arrangements (OBAs)
- Value-Based Arrangements (VBAs)
- Value-Based Payment Arrangements (VBPs)

Example of OBAs:

- **Outcome-** For a blindness gene therapy, the contract could measure short- and long-term durability of the drug based on vision tests; if the patient's vision does not improve, then the manufacturer refunds a percentage of the cost of the drug back to the payer
- **Adherence-** For an end-of-life cancer drug, adherence/refill data could be measured as a proxy to show that the drug is extending life (i.e., more refills indicates the patient is still alive) and if the patient pass a pre-determined marker, the manufacturer is reimbursed.

Medicaid & OBAs:

In order to establish an OBA at the state level, Medicaid agencies need to submit a state plan amendment (SPA) to CMS that allows them to use supplemental rebate agreements for OBAs. Eight states have submitted SPAs and received approval. Several of those states have already implemented OBAs with manufacturers.

Federal Barriers to OBAs:

The Centers for Medicare and Medicaid Services (CMS) acknowledges that OBAs can "assist states with providing Medicaid patients access to needed therapies while providing a payment arrangement that allows the state flexibility, including an option to only pay when a therapy actually works."¹ However, federal price reporting laws (Medicaid Best Price and Average Manufacturer Price [AMP]) and fraud and abuse laws (Anti-kickback Statute [AKS] and Stark) inhibit OBAs. Specifically, if a patient does not respond to a therapy and a significant refund is provided to the payer, this could skew the Best Price and AMP of the therapy. A skewed Best Price and AMP will result in inaccurate Medicaid rebates. Additionally, manufacturer refunds in this case could potentially trigger AKS and the Stark law because the manufacturer could be viewed as giving an inducement. CTT believes changes to federal statute are critical to ensure patients have access to rare disease gene therapies.

¹ <https://www.federalregister.gov/documents/2020/06/19/2020-12970/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and>