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M E M O R A N D U M

DATE: October 23, 2019
TO: Wisconsin Pharmacy Cost Committee
FROM: Kirk Williamson, Kate Johnson, Sandra Wilkniss, NGA Health
RE: State Value-Based Purchasing Agreements with Biopharmaceutical Manufacturers

This memo was produced for the Wisconsin Pharmacy Cost Committee to provide the current status of value-based purchasing (VBP) arrangements between payers and pharmaceutical manufacturers. The memo provides 1) current impressions of the utility of VBP approaches in pharmaceuticals; 2) a brief description of different types of value-based purchasing approaches pursued by payers and manufacturers and historical context for these approaches; 3) state examples of VBP arrangements in Medicaid; and 4) a brief summary of commercial VBP arrangements between plans and pharmaceutical manufacturers.

Value-Based Purchasing in Pharmaceuticals

Consistent with the overall trend toward paying for value over volume in the U.S. healthcare system, payers are extending the VBP model into their pharmaceutical purchasing approaches. While there is clear interest in this approach, progress has been slow and those with experience note limitations in how far this approach can go toward solving the problem of prescription drug affordability in the U.S. Both commercial and public payers agree the main limitation is that negotiations begin with prices set by manufacturers.[i] For states, other challenges include: finding agreement with manufacturers on meaningful and measurable metrics (including limiting measurement to variables available in claims data), limited state capacity to engage in robust negotiations relative to well-resource industry partners, d modest savings against costs associated with implementation and effective oversight of negotiated arrangements. Still uptake continues, including around extremely high-priced drugs with curative potential because restricting access is not possible (e.g., for those participating in the Medicaid Drug Rebate Program) nor desirable, leaving payers to seek financing solutions.[ii]

VBP arrangements can take many forms, and may be defined slightly differently by various entities, but the arrangements generally fall into two categories: outcomes-based and finance-based.

- **Outcomes-based arrangements –** Outcomes-based arrangements link payment to an agreed upon performance metric. Accountability for results is based on clinical or quality of care outcomes (including adherence) and may also include additional utilization or spending/cost metrics.
- **Finance-based arrangements –** Finance-based arrangements link payment to financial measures and utilization. These arrangements are designed to improve cost predictability but are not linked to health outcomes and typically involve setting a volume for price tradeoff.

State-based VBP arrangements, whether outcomes- or finance (volume)-based are still relatively new, and more evidence is needed to define parameters for pursuing. Example provided below are illustrative of arrangement currently being implemented and lessons learned to date.

States and Outcomes-Based VBP Arrangements in Medicaid

Oklahoma, Colorado and Michigan are the first state Medicaid programs that have received approval from the Centers for Medicare and Medicaid Services (CMS) to enter into outcomes-based arrangements with biopharmaceutical manufacturers. On June 27, 2018, CMS approved Oklahoma's state plan amendment (SPA) authorizing the state to enter into outcomes-based contracts with manufacturers in which the manufacturer will pay greater supplemental rebates if agreed upon outcome metrics are not achieved. Oklahoma has since executed four contracts and one collaborative agreement with five different manufacturers. Importantly, these arrangements are excluded from the "best price" provision under the Medicaid Drug Rebate Program (MDRP). Both Michigan and Colorado subsequently received approvals from CMS for state plan amendments authorizing them to enter into outcomes-based contracts with manufacturers. To date, neither state has publicly declared that it has entered into a VBP contract with a manufacturer.

Oklahoma

Oklahoma is the first state to enter into VBP arrangements with manufacturers. The state received assistance with contract design from the National Academy for State Health Policy and with its SPA application from the Center for Evidence-Based Policy's State Medicaid Alternative Reimbursement and Purchasing Test for High-Cost Drugs (SMART-D) Project. As of May 2019, Oklahoma Medicaid (which is 100 percent fee-for-service) initiated conversations with over 30 manufacturers and have executed five VBP contracts and one collaborative agreement with five different manufacturers. Current contracts include those with:

- Alkermes for aripiprazole lauroxil (Aristada), a long-acting injectable antipsychotic drug. Under this arrangement, the price of the drug decreases as patient adherence targets are met. The arrangement did not include any explicit requirements related to case management to support improved adherence.
- Melinta for oritavancin (Orbativ), an IV antibiotic used to treat bacterial skin infections. Under this arrangement, the state removed prior authorization on the drug in exchange for the assurance that Orbativ will not produce net increases in overall costs of care.
- Eisia for Fycompa, an anti-epileptic drug, with reduced hospitalizations as the target metric.
- Jannsen for Invega Trinza and Sustenna, long acting, injectable antipsychotic, to improve overall population adherence.
- Novartis for Zolgensma, a gene therapy used to treat children less than 2 years old with spinal muscular atrophy. Under this arrangement, the price of the drug decreases if patients die or require permanent ventilation.

The state also has entered into a collaborative agreement with Amgen to explore whether they can identify products to target for VBP agreements.

Based on Oklahoma's experience to date, state officials and other experts have observed several challenges and lessons learned in pursuing these types of VBP arrangements:

- The number of drug classes indicated for VBP arrangements may be limited due to challenges related to meaningful outcomes measurement. To date, metrics included in VBP contracts have been those that can be assessed using Medicaid claims data. Electronic health record data remain difficult to access, analyze and incorporate, resulting in a lack of clinical outcomes metrics.

- Cost-benefit analyses of whether to pursue VBP arrangements should consider the amount of additional rebates collected or costs avoided weighed against increased costs associated with data collection, analysis and management of the agreement.
    - None of the contracts in Oklahoma have yet been fully evaluated, and the state doesn't expect to complete its analyses before January 2020.
- Few manufactures have engaged in the process to date. Smaller manufacturers may be more nimble or have different incentives than larger manufacturers under current VBP scenarios. In general, manufacturers of high-cost drugs have little incentive to take on risks associated with these contracts (until significant competition arises).

    ** **Note**: One exception is Novartis and Zolgensma, a gene therapy for spinal muscular atrophy. Novartis has developed an outcomes-based contract model that the manufacturer is shopping around to payers, including state Medicaid programs. In exchange for an expedited prior authorization process and widespread newborn screening, they are offering an arrangement involving payment in installments over 3-5 years and graduated discounts over time in the event of death or permanent ventilation.
- As with all contracted arrangements, trust and mutually-beneficial risk arrangements will take time to develop – the agreements are complex and require significant data analysis to inform both outcome targets and financing approaches.
- A governance structure for the contracting process is essential to usher along the process and delineate roles for each relevant party to inform ongoing negotiations.
- Legal analysis is important to determine the impact of proposed agreements on Medicaid "best price" rules or anti-kickback statutes.
- Negotiations may be less complex under Medicaid fee-for-service payment models than managed care payment models.

Massachusetts

In addition to the work underway in Oklahoma, Colorado, and Michigan, Massachusetts is encouraging VBP arrangements under its new policy of making a separate payment for certain high-cost specialty drugs and biologics outside the bundled payment provided to hospitals. As a condition of making this separate payment, the state requires hospitals to make a concerted effort to enter into an outcomes-based arrangement with the manufacturer, if the manufacturer offers such an arrangement. All new-to-market drugs and biologics not currently placed on the MassHealth Drug List will be evaluated on a case-by-case basis to determine if the drug should be subject to a separate payment, for which a VBP arrangement could be reasonably pursued.

States and Finance-Based (or volume-based) VBP Arrangements

Louisiana and **Washington** have been forerunners in developing capped financing models for Hepatitis C drugs. The approach, often referred to as a "subscription model" involves an agreement with a manufacturer in which the state pays a negotiated price for unlimited volume of their drug over a specified period of time. The models are focused on increasing access in a way that recognizes serious budget constraints and have the potential to help states establish budget predictability, amortize spending and negotiate significant discounts for volume trade-offs with manufacturers. Louisiana and Washington have entered into these arrangements as part of their broader objectives to eliminate Hepatitis C and both states have built arrangements that involve their Medicaid and corrections populations. Under the arrangements, total spending on a manufacturer's Hepatitis C drug is capped at a negotiated amount and an unrestricted supply is

made available to the state Medicaid and corrections populations. The state models vary slightly and both states sought and received approval from CMS for SPAs to enter into these arrangements.

Louisiana reached a deal with Asegua Therapeutics, a subsidiary of Gilead Sciences and Washington has contracted with AbbVie. Washington's arrangement is part of its broader Hep C Free Washington Plan to Eliminate Hepatitis C . The arrangements both include an unrestricted supply and an expenditure cap (versus an upfront payment), which when reached, the manufacturer provides the drug for a nominal amount. Notably, Washington has also structured its arrangement whereby AbbVie provides support for certain on-the-ground HCV elimination strategies including coordinating with the state to find individuals who are not yet treated; educating the health care workforce about screening and providing curative HCV treatment; and addressing barriers to care such as stigma, lack of urgency to treat among patients and providers, and access to HCV specialists. Ultimately, states can structure a subscription payment or other finance-based models in different ways, each of which offers unique benefits and can be more or less challenging to implement. Determining which products are appropriate for such models, the time frame of the arrangement, the payment level and structure, and the agreed-upon volume are critical components of this approach.

Commercial VBP Arrangements

Private insurers and health systems have much more experience with outcomes-based contracting for pharmaceuticals than states. The chart below (Table 1 from this report) highlights some examples of publicly disclosed contracts in the commercial market. More recent arrangements include reimbursement linked to much broader outcomes – which, according to some, may set the stage for the next wave of outcomes-based contracts with increasing pressure on pharmaceutical manufacturers around questions of affordability. Examples of more recent arrangements include:

- Harvard Pilgrim Health Care negotiated an outcomes-based contract with Spark Therapeutics that links payment for Luxturna, a new gene therapy for an inherited form of blindness, to measured improvement in patients at 30 to 90-day intervals and again at 30-months.
- University of Pittsburgh Medical Center (UPMC) Health Plan announced a deal with Boehringer Ingelheim around Jardiance, a type 2 diabetes drug indicated to reduce risk of cardiovascular mortality in that population. The arrangement links payment to the total costs for all people with diabetes treated (not just those with cardiovascular disease).
- UPMC also entered into a contract with AstraZeneca (which reports more than 40 value-based agreements across therapeutic areas) for Brilinta, a heart-attack prevention treatment. Under the contract, this brand drug is offered on the plan's generic tier and payment is linked to cardiovascular outcomes when treatment follows recent hospitalization for heart attack or unstable angina.

Table 1

Examples of Publicly Disclosed Outcomes-Based Pharmaceutical Contracts in the U.S.

Drug	Manufacturer	Payer(s)	Disease area	Outcome metric and terms	Date
Entresto/ sacubitril, valsartan	Novartis	Aetna	Congestive heart failure	Additional rebate given if the drug does not achieve the heart failure admissions reductions it achieved in clinical trials.	Spring 2016
Repatha/ evolocumab	Amgen	Harvard Pilgrim	Hyper-cholester-olemia	Upfront discounts and future rebates given based on meeting specific cholesterol targets, total spending threshold, and adherence in exchange for preferred formulary placement.	Spring 2016
Repatha/ evolocumab	Amgen	Harvard Pilgrim	Hyper-cholester-olemia	Full refund if patient has a heart attack or stroke.	Spring 2017
Rebif/ interferon beta-1a	Merck KGaA	Prime Therapeutics	Multiple sclerosis	Rebates given if patients on the drug have total costs to their plans higher than patients on a different MS drug, or if the medication adherence rate reaches a specified level.	March 2011
Januvia and Janumet/ sitagliptin/ metformin	Merck & Co.	Cigna	Diabetes	Rebates given if a specified A1c blood sugar level is not met in the patient population. The agreement is also contingent on good adherence.	April 2009

Data: Authors' analysis.
Source: E. Seeley and A. S. Kesselheim, *Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending?* The Commonwealth Fund, September 2017.

[i] https://www.modernhealthcare.com/insurance/cure-high-drug-prices-outcomes-based-deals-arent-delivering-yet

[ii] Ibid. And personal communication from Michigan.